Exhibit #1

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Le infezioni nella storia della medicina

Infections in the history of medicine

From miasmas to germs: a historical approach to theories of infectious disease transmission

Dai miasmi ai germi: un approccio storiografico alle teorie della trasmissione delle malattie infettive

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INTRODUCTION

Throughout centuries philosophers and scientists tried to explain the way of infectious diseases transmission. Witchcraft, demons, gods, comets, earthquakes were the first unproved theories, followed by tangible scientific ones such as miasma's theory, contagious theory, spontaneous generation theory and germ theory till the evolution of microbiology in mid 19th century.

Early transmission theories and the miasma theory

Primitive ideas about contagiousness dealt with the general notion of transmission through contact. Epidemics were probably rare in small primitive tribes but they became terrifying events once population density increased enough to produce and sustain them. At that time people's ignorance led to magical or religious explanations of disease, sent by the gods as punishment for their sins [1]. Among many primitive tribes, as well as in the highly developed sacerdotal practices of ancient cultures, we find suggestive fragments of infectious diseases transmission embedded in a matrix of religion [2, 3]. Characteristically, in Ancient Persia we see an emphasis on demonology. The disease is caused by evil spirits and must be controlled by exorcism. The cult of Nergal, a demon portrayed in hymns and myths as a god of war, fever and pestilence, was of a great importance [4]. In Ancient Rome fever had three temples, in Palatine Hill, in Vicus Longus and in Sacra Via and was supplicated as the Goddess Febris who protected people from fever and malaria [5].

In 6th century BC, the pre-Socratic philosophers Pythagoras, Alcmaeon, and Empedocles inaugurated the period in science where the environment was understood to play a vital role in health and disease. A century later, *Airs, waters and places* of the Hippocratic texts, correlated a variety of symptoms and diseases with geographical and meteorological conditions, for example malaria, catarrh and diarrhea were believed to be due to the effect of seasonal changes on stagnant water or marshy places [6]. Such concepts survived and in time consolidated in the belief that a pathological state of the atmosphere is associated with infectious diseases and this line of thinking developed further into the miasma theory of contagion [7]. Air became contaminated with "miasmas", poisonous vapors produced by putrefying organic matter and a person could become infected when miasmas invaded the body and disturbed its vital functions.

In his manuscript about hygiene-based regulation for selecting building sites, entitled *De architectura*, the Roman architect Marcus Vitruvius Pollio (70 BC-15 BC) revokes the miasma theory and warned against swampy places: "For when the morning breezes blow toward the town at sunrise, if they bring with them

mist from marshes and, mingled with the mist, the poisonous breath of creatures of the marshes to be wafted into the bodies of the inhabitants, they will make the site unhealthy" [8]. Galen (130- c. 201 D) the most famous physician of the Roman period emphasizes also the miasma theory as he recognizes plague, tuberculosis and skin diseases as contagious [9].

As we pass from the classical to the early centuries of the Christian era, we find the contagiousness of leprosy playing a major role in the basis of the Old Testament. In *Leviticus Book*, a sanitary code almost free from any elements of supernaturalism, we notice a system for controlling leprosy involving differential diagnosis, isolation, quarantine and disinfection that remains the most brilliant application of rational epidemiology of ancient times. In the Byzantine period the spread of leprosy is also mentioned in the writings of Aretaeus of Cappadocia (1st century AD). He states that the breath is the vehicle for disease transmission. In the 6th century AD the bubonic plague epidemic also named "Justinian Plague" furnished new information's to the concept of contagion [10]. The historian Evagrius Scholasticus (537-594) described the plague and considered it transmitted by contact, visiting infected houses or even by interpersonal relationship in the market place [2].

The contagious theory of Girolamo Fracastoro

In the medieval period epidemic disease was associated in people's mind with comets, eclipses, earthquakes or major astrological disturbances that charged the air with poisonous vapors known as "miasmas". The miasma theory was again the dominant theory of contagion because of people's observation that the epidemics and mainly the plague tended to occur during the hot summer months where the air in the cities was humid and filled with the odours of garbage, decomposing animals and human waste.

During the 16th century, Girolamo Fracastoro (1478-1553) poet, physician and mathematician attempted to analyze the concept of contagion and infection. In his major clinical work *On Contagion, Contagious Diseases and Their Cure*, published in 1546, Fracastoro distinguished three forms of contagion and speculated that infections are caused by transferable seed-like beings, seminaria or germs, which could cause infection. Having observed the epidemics of syphilis, plague and typhus that devastated Italy during the16th century, Fracastoro introduced his own theory of disease, the contagious theory. According to his writings, some diseases, such as syphilis and gonorrhea were only transmitted by direct contact, other diseases were transmitted by fomites as clothing, that had been in contact with the sick and in the third category he placed diseases such as tuberculosis and smallpox capable of infecting persons at a distance from the sick and transmitted by air [1]. For Fracastoro, germs are conceived not as living microorganisms but as chemical substances liable to evaporation and atmospheric diffusion; each disease was specific and had its specific germ; the germ propagated in the tissue of the infected host and caused disease by setting up chemical putrefactive changes in those tissues; in order a germ to produce infection, it must find a corresponding analogy in the tissues of the host [11].

Fracastoro's theory is considered to be the first theoretical statement of the contagious theory of the disease, three centuries before Pasteur's and Koch's researches, a victory of rationalism but in that period a difficult concept for people to accept; they continued to believe in the miasma theory that persisted well into the 1800s.

From spontaneous generation to germ theory

Despite the discovery of the microscopic world by Anton van Leeuwenhoek (1632 – 1723), in the 17th century little progress had been made on the road to truth and reason. In that historical period the revival of the spontaneous generation theory was widely accepted by most members of the scientific community. It proposed that simple life arises spontaneously from non living matter (abiogenesis); for example mice can arise from grain and maggots from decaying meat. The idea of spontaneous generation may be tracked back in the teaching of Aristotle in 4th century BC. According to this theory stated in *The History of Animals* and in The *Generation of Animals*, living things came from non living things because the non living material contained pneuma or vital force [12].

A strong opponent to that theory was the Italian physician Francesco Redi (1626-1697). In his work entitled *Experiments on the Generation of Insects*, published in 1668, he developed an experiment in order to disprove that maggots arose spontaneously from decaying meat (Figure 1). Redi began by putting pieces of meat into six jars, he covered with lids three of the jars and he left open the other three. The meat in the closed jars decayed but no maggots appeared;

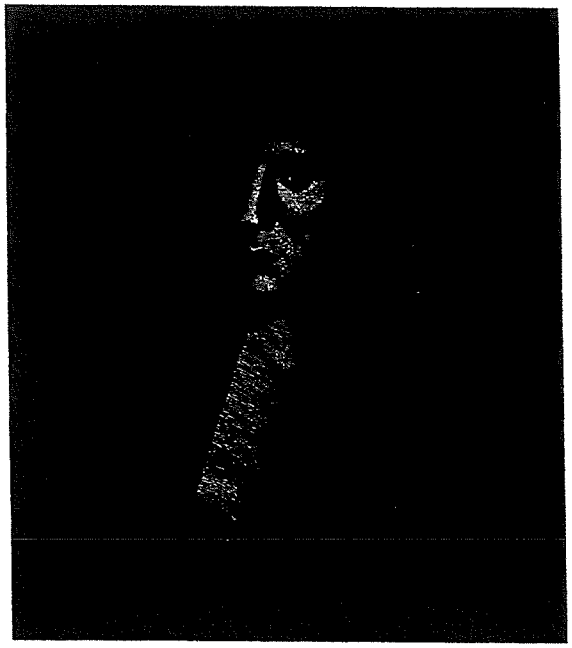

Figura 1 - The eminent Italian physician Francesco Redi (1626-1697).

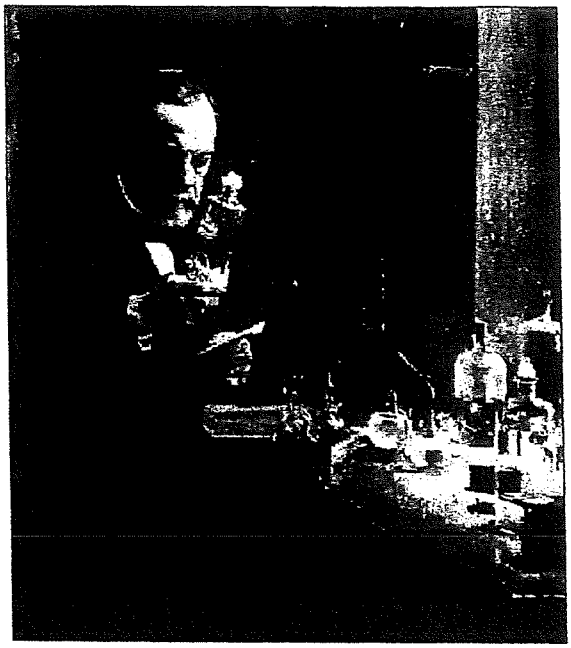

Figura 2 - The French chemist and microbiologist Louis Pasteur (1822-1895).

however maggots and flies appeared in the opened jars. His experiment did not convince the supporters of the spontaneous generation theory which argued that it was unauthentic; the lids excluded air and therefore the "vital" force necessary for spontaneous generation to occur. Redi modified his experiment by putting nets instead of lids on the same jars and no maggots appeared. These results gave a strong blow to the spontaneous generation theory but many scientists still believed that microscopic forms of life were generated from non living substances [13, 14].

The theory of spontaneous generation was finally putting to rest in 1862 when the French chemist Louis Pasteur (1822-1895) proposed a germ theory of diseases, supporting that microorganisms are the cause of diseases (Figure 2). Actually, during that period scientists were working on the notion of the species trying to identify life. If Charles Darwin (1809-1882) went to Galapagos and he theorized on the birth of a new world and on the evolution of species, Pasteur was riveted to his microscope revealing the origin of germs [15].

During 1862 and 1864, Pasteur was working on ferments, carrying out revolutionary experiments and making observations that disproved the spontaneous generation: "Among the questions raised by my research on the ferments in the narrow sense, none are more worthy of attention than those relating to the origin of ferments. Where do they come from these mysterious agents? This is the problem that has led me to study the so-called "spontaneous generation" [15]. He demonstrated that fermentation and growth of microorganisms in nutrient body did not proceed by spontaneous generation. He boiled meat broth in a flask, heated the neck of the flask in a flame until it became pliable, and bent it into the shape of an *S*. Air could enter the flask, but airborne microorganisms could not, they would settle by gravity in the neck. As Pasteur had expected, no microorganisms grew. When he tilted the flask so that the broth reached the lowest point in the neck, where any airborne particles would have settled, the broth rapidly became cloudy with life [16]. Pasteur had both refuted the theory of spontaneous generation and demonstrated that microorganisms are everywhere, even in the air; the revolutionary germ theory was a reality [17].

Finally, it was a German scientist Robert Koch (1843-1910) who developed the criteria and procedures necessary to establish that a particular microbe and no other cause a particular disease. His first demonstration with the anthrax bacillus was in 1876. Between 1877 and the end of the century he identified tuberculosis bacillus and vibrio cholerae. In 1884 Koch and Friedrich

Loeffler (1852-1915) formulate four criteria in order to establish a relationship between a causative microbe and a disease. According to this, the microorganism must be found in abundance in all organisms suffering from the disease, but should not be found in healthy animals, it must be isolated from a diseased organism and grown in pure culture, the cultured microorganism should cause disease when introduced into a healthy organism and a microorganism must be re-isolated from the inoculated, diseased experimental host and identified as being identical to the original specific causative agent [18]. The modern concept of disease transmission was born.

CONCLUSION

The concept of disease transmission and contagion was well established before microorganisms were identified. As the conception upon diseases transmission reflects the society's state of progress, we passed from the miasma theory to the most important concept in the history of modern medicine, the germ theory.

Key words: miasma theory, Girolamo Fracastoro, spontaneous generation, Louis Pasteur.

Conflict of interest: none

SUMMARY

From miasma to germ theory we trace the evolution of conceptions in infectious disease transmission. Starting from the unproved theories of contagiousness we move on to miasma theory, contagion theory and spontaneous generation theory up to the revolutionary germ theory of disease transmission.

RIASSUNTO

In questo articolo viene tracciata l'evoluzione del concetto di trasmissione delle malattie infettive. Partendo dalla teoria non provata della contagiosità, e passando attraverso la teoria dei miasmi, del contagio e della generazione spontanea, gli autori giungono infine a discutere della teoria "rivoluzionaria" dei germi.

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Exhibit #2

REPORT OF THE INTERNATIONAL PLAGUE CONFERENCE

HELD AT

MUKDEN, APRIL, 1911

MANILA
BUREAU OF PRINTING
1911

It has been suggested that toward the close of the epidemic involution forms of the bacillus were often observed in the sputum and blood of the cases infected and that this was an evidence of the loss of general virulence of the organism. Poorly-staining and swollen, degenerated forms of the plague bacillus are frequently found in cases of most acute and virulent infection and may be the result of the struggle between the serum of the host and the invading organism; they depend particularly upon the immunity of the host. In every infection a number of bacteria always become degenerated, show plasmolysis, or are killed in the attempt of the serum and cells of the host to overcome the infection. The presence of these degenerated forms may have no significance in regard to the virulence of the infecting organism, as may be proved by inoculation experiments performed with it.

VITALITY OF THE BACILLUS ON INANIMATE BODIES

Resistance to exposure.—The pneumonic strain was found to be destroyed after an exposure of one minute to 0.1 per cent sublimate solution and after ten minutes' exposure to 1 per cent carbolic acid or to 1 per cent lysol solution. When sputum containing the organism was smeared upon glass and exposed to direct sunlight, it was destroyed in from two to five hours, according to the thickness of the layer of sputum. When the sputum was exposed to the air, but not to sunlight, the organism was destroyed in from eighteen to twenty-one hours. When smeared upon cloth and exposed to the sunlight, the sputum was found to be sterile after five days.

The pneumonic strain was found to be destroyed in peptone solution after heating at a temperature of 60° C. for ten minutes in a water bath. On the other hand, it was shown that successive freezing and thawing of the organism not only did not destroy it, but that it apparently retained its complete virulence afterward and caused the death of guinea pigs, sometimes in three or four days, after cutaneous infection with it. Kasansky[1] has shown that *Bacillus pestis* still remained alive after being exposed to temperatures varying from 2° to —31° C. for periods of from three to five and one-half months. In many instances, plague bacilli were isolated, during the recent epidemic, from exhumed corpses which had been buried for three months, and in one instance for six months, the corpses having remained frozen during this time.

[1] *Centralbl. f. Bakt. etc.*, 1 Abt. (1899), 25, 122. *See also* Verjbitski, *Journ. Hyg.* (1908) 8, 203.

INFECTIVITY OF THE PLAGUE PATIENT

INFECTIVITY OF THE EXCRETA

In no other disease is the infecting organism found in such abundance in the sputum as it is in pneumonic plague. When the disease is well developed, *Bacillus pestis* is present in almost pure culture. In pneumonic plague as in bubonic plague, when the disease becomes septicæmic, the organisms are sometimes found in the urine and even sometimes in the faeces, but in pneumonic plague the sputum always contains large numbers of plague bacilli at the time when it becomes well tinged with blood. When once the sputum of pneumonic-plague cases becomes thoroughly dried it is no longer infectious, but when the sputum becomes frozen and pulverized, particles of it may be blown about and remain infective for long periods of time or until the sputum is again thawed.

INFECTIVITY OF THE BREATH

In regard to the manner of infection during the epidemic, studies were carried out to show, first, whether in cases of pneumonic plague pest bacilli become disseminated into the air by the expired air or vapor arising from the breath, as in ordinary or dyspnœic respiration, and, secondly, whether the organisms are disseminated by moderate attacks of coughing in pneumonic cases in which the cough did not result in the expulsion of particles of sputum visible to the naked eye. These questions were studied extensively by means of exposing plate cultures before the mouths of undoubted plague cases and of then identifying the organisms which developed on the plate cultures by the usual methods and particularly by animal inoculations. Guinea pigs, the abdomens of which had been freshly shaven and scarified, were also exposed before the mouths of pneumonic-plague cases.

The conclusions arrived at from these experiments are as follows:

Conclusions.—During normal and dyspnœic respiration of primary pneumonic-plague cases, plague bacilli are not usually expelled by means of the expired air.

During coughing of such cases, even when sputum visible to the naked eye is not expelled, plague bacilli in large numbers may become widely disseminated into the air surrounding the patient.

The distance from the patient, that the air may become infected by droplets containing plague bacilli, varies largely with the strength of the cough, the amount of mucus in the throat and larynx at the time, and the currents of air in circulation in the ward.

The idea that infection of doctors, nurses, attendants, etc., in plague

hospitals, is caused entirely by particles of sputum expectorated by the patient and visible to the naked eye is erroneous. It follows from these experiments that the wearing of masks and the proper covering of any surface of the skin where fresh abrasions are present are important, personal, prophylactic measures in pneumonic plague. It also follows that the eyes should be protected against this manner of conjunctival infection by proper glasses.

Articles of clothing worn in the wards should immediately be sterilized after removal, since, even though no particles of sputum may be visible upon them, plague bacilli may be present.

In the case of infection by inhalation the risk to the person exposed bears a direct relation to his proximity to the patient and the duration of exposure.

From these experiments it is very evident how dangerous an infective agent a pneumonic-plague patient is. In no other disease is the individual so dangerous and in no other disease does the danger from droplet infection approach that which exists in pneumonic plague. The number of plague bacilli expelled in droplets, from pneumonic-plague cases, is far greater than the number of bacilli ever expelled by patients afflicted by tuberculosis, croupous pneumonia, diphtheria, or influenza.

INFECTIVITY OF CORPSES

It was repeatedly shown that *Bacillus pestis* still remained living and virulent in corpses of patients who had succumbed to pneumonic plague and that had remained frozen upon the ground for three months, or in those which had been exhumed after burial for the same length of time. Human bones have been found in the burrows of tarbagans. Infection of rats and tarbagans from gnawing infected corpses both buried and unburied must, therefore, be considered as a possible source of plague. In putrid animals, the plague bacillus usually does not live longer than one week, but in one instance this organism was found to be present one month after death. In view of the length of time during which plague corpses may remain infective, complete cremation should be carried out. Also, in time of plague, the carrying and shipment of corpses should be prohibited.

INFECTIVITY OF FLEAS

No evidence was presented during the Conference showing the infectivity of fleas during the epidemic. Plate XVIII, Part I, page 66, showing the seasonal prevalence of rat fleas, indicates that fleas were not prevalent upon rats during the season in which the epidemic prevailed. Moreover, there was no evidence that rats became infected during the epidemic. No fleas were observed upon the pneumonic-plague patients.

BACTERIOLOGICAL DIAGNOSIS OF PNEUMONIC PLAGUE

EXAMINATION OF THE SPUTUM

A bacteriological diagnosis from the sputum can not be made at the onset of the disease, and not until after the fever has developed does the sputum appear. Shortly after the appearance of the sputum the plague-organism, even if not visible from the microscopical examination, may be isolated by culture. When the sputum becomes bloody, the organism is usually present in large numbers and in almost pure culture. Sometimes the organism might be mistaken morphologically for *Diplococcus pneumoniæ*, and bipolar-staining organisms, other than plague bacilli, may sometimes be encountered in the sputum. While in the microscopical examination of the sputum Gram's stain is a very valuable aid in arriving at a diagnosis of the organism, nevertheless, Gram-negative bacilli have been encountered in the sputum, which proved later not to be plague bacilli. However, usually if the sputum is blood-stained, from the microscopical examination, with the aid of Gram's stain, there is no difficulty in arriving at a diagnosis, since the plague organism is usually present in such very large numbers. In the later stages of the disease, involution forms are commonly encountered in the sputum. The organisms are constantly found in great abundance up to the time of death.

BACTERIOLOGICAL EXAMINATION OF THE BLOOD

In the early stages of the disease, cultures from the blood are frequently negative. Sometimes, however, the organism could be cultivated from the blood from twenty-four to forty-eight hours before death, and it could always be obtained from the blood a few hours before death. In many instances the bacteria are present in very large numbers in the blood, so that a diagnosis can often be made from a simple, microscopical examination. In no other disease is so marked a bacteræmia present. In the early stages of the disease cultures from the blood should be made in bouillon, as much as 1 cubic centimeter of blood being employed. The agglutination test is of no value in making a diagnosis, as the course of the disease is too acute and the patient has succumbed before the agglutinins appear in demonstrable quantities. The reaction of the deflection of the complement is also not to be recommended for the same reason; the examination of the sputum and blood for the presence of the bacillus gives much greater and more valuable information. In cases where

Exhibit #3

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THE PHILIPPINE JOURNAL OF SCIENCE

SECTION B

THE PHILIPPINE JOURNAL OF TROPICAL MEDICINE

RICHARD P. STRONG, PH. B., M. D.
EDITOR

MANILA
BUREAU OF PRINTING

STUDIES ON PNEUMONIC PLAGUE AND PLAGUE IMMUNIZATION.

XII. SOME EXPERIMENTS TO DETERMINE THE EFFICACY OF VARIOUS MASKS FOR PROTECTION AGAINST PNEUMONIC PLAGUE.

By M. A. Barber and Oscar Teague.

(From the Biological Laboratory, Bureau of Science, Manila, P. I.)

During the epidemic of pneumonic plague which raged in Manchuria during the winter of 1910 to 1911, it was believed and, toward the close of the epidemic, was experimentally demonstrated, by Strong and Teague, that sputum in the form of invisible droplets containing viable plague bacilli was frequently suspended in the air near the coughing pneumonic-plague patients. A Petri dish, containing solidified agar-culture-medium, held for a minute or two before the mouth of a patient and closed after a single cough did in some instances on incubation show numerous colonies of plague bacilli, although no visible particles of sputum had been thrown against it.[1] There was every reason to believe that even the smallest number of these bacilli inhaled into the lung would lead to infection and that this was, in fact, the common mode of infection in pneumonic plague. The obvious method to protect against such infection was to interpose a barrier to the passage of these droplets into the mouth and nostrils. With this object in view, masks were worn quite generally by physicians and attendants when in the presence of plague patients or suspected cases. That protection was afforded by the masks apparently went unquestioned and, without the sense of security that their use gave, the mental strain in connection with the work would have been almost unbearable.

The total number of deaths that occurred among physicians,

[1] Report of the International Plague Conference held at Mukden, April, 1911. Manila (1912), 88. See also II, p. 137 of this report.

nurses, attendants, and inspectors during the recent epidemic of pneumonic plague in Manchuria will never be known. The following death roll at Fuchiatien, the Chinese city near Harbin, shows that the total must have been extremely high.

List of deaths of antiplague staff at Fuchiatien.[2]

Doctors	1 out of 20
Students	1 out of 29
Native practitioners	4 out of 9
Police inspectors	2 out of 31
Police	30 out of 688
Sanitary police	11 out of 206
Mounted police	5 out of 80
Firemen	5 out of 20
Coolies	102 out of 550
Cooks	4 out of 60
Ambulance parties	69 out of 150
Soldiers	63 out of 1,100
Total	297 out of 2,943

In South Manchuria the plague sanitary corps suffered a loss of 122 persons among whom were 1 Japanese, 1 English, and 40 Chinese physicians. This represents 2.66 per cent of the total plague mortality in the districts concerned.[3]

The presumption is that all of the members of the sanitary corps wore masks. The masks were, however, not worn constantly nor were they always properly adjusted; coolies were often seen with the masks hanging around their necks instead of being over their mouths. Hence the high death rate of the sanitary staff can not be regarded as proof of the inefficiency of masks.

In Mukden the mask which was almost universally employed consisted of a pad of absorbent cotton about 16 by 12 centimeters and about 1.5 centimeters thick; this was wrapped in gauze, the ends of which were tied at the back of the head. (See Plate V, fig. I. B.) A many-tailed bandage (see Plate V, fig. I. A) composed of three layers of gauze with holes for the eyes was tied around the entire head and served to press the mask firmly against the face and to keep it snugly in place for hours at a time. When first put on, this mask was decidedly uncomfortable, but after a few minutes one became somewhat accustomed to it and could wear it for two or three hours at a time. There was, however, always an intense feeling of

[2] *Ibid.*, p. 242.

[3] *Ibid.*, p. 244.

relief on removing it. We shall designate this type of mask in the discussion to follow as the "Mukden mask." [4]

The following experiments were undertaken with the idea of determining whether this Mukden mask is, in fact, an efficient barrier against the passage of plague bacilli into the lungs and, also, whether or not other types of masks are more efficient.

At the International Plague Conference held in Mukden in April, 1911, Broquet, the French delegate, demonstrated a mask "copied from those used by doctors in the epidemic of the fourteenth century as shown in old books." [5] It consisted of a hood of light canvas or khaki cloth, covering the entire head and drawn in at the neck. In front was a window of mica. No experiments had been performed to test the efficacy of this mask. We shall refer to this type of mask hereafter as the "Broquet mask." It was not used during the recent epidemic of pneumonic plague in Manchuria with the exception of a few times by Broquet himself.

Our preliminary tests indicated that a hood of heavy Canton flannel with a nap was more effective in holding back *Bacillus prodigiosus* than hoods of lighter cloth such as the one demonstrated by Broquet. Instead of mica for the window, we used sheet celloidon such as one sees in the storm curtains of automobiles. The hood was made narrow at the neck so that it would spread out over the shoulders and could be drawn in and tied snugly around the neck. Comparative experiments were made with this mask and the Mukden mask; the subjects wearing the two masks were forced to breathe air containing *Bacillus prodigiosus* simultaneously for the same length of time.

Bacillus prodigiosus was selected for the experiments as being entirely harmless and easily recognizable on account of its pigment production. An ordinary throat atomizer was used for making the spray, but with the idea of getting smaller droplets the rubber bulb was removed and a stronger airblast was obtained by using an automobile pump.

Special precautions were taken to avoid accidental contamination with *B. prodigiosus* on removing the mask. (See Plate V, fig. 2.) The subject was clothed in an operating gown and, in the case of the Mukden mask, his head was covered with a cloth and the eyes protected by automobile goggles. The spraying was generally done in a small, single-roomed stable which

[4] We were informed that this mask was extensively used in Harbin before its introduction into Mukden.

[5] Report of the International Plague Conference, p. 303.

was boarded up on all sides to keep out the light and to avoid, to a certain extent, currents of air. The gowns, goggles, and head-cloths were removed after the subjects had left the stable and before they entered the laboratory building. One of the authors attended to the spraying and exposure of the subjects, the other endeavored to keep himself and his laboratory room free from *B. prodigiosus* and made the necessary plate-cultures in order to determine the result of the test. At first the saliva, taken before and after the spraying, was smeared over agar plates, but later it was found that small pieces of moistened cotton, placed in the nostrils and before the mouth (underneath the Mukden mask), rendered the test much more delicate.

Agar plates were exposed during the course of the experiment in order to obtain an indication of the *living* prodigiosus bacilli that were in the air around the mask at that time.

The following protocols, selected from a long series of such experiments, demonstrate the general mode of procedure and the results obtained.

PROTOCOL NO. 1. (EXPERIMENT NOS. 97 AND 98.)

Two laboratory boys[6] served as subjects. Control plates were made as follows: A quantity of saliva was expectorated into a plate containing solidified agar, distributed by means of a sterile cotton plug, and a small

[6] The first experiment was performed upon ourselves to demonstrate the harmlessness of the procedure. Then several of our colleagues and about 8 different laboratory boys served as subjects in these experiments. Yet, owing to the large number of experiments that were done, it was found necessary to use the same laboratory boys repeatedly as subjects. However, a period of at least a week was allowed to elapse before a boy was again called upon to serve, and then smears were made from nostrils and saliva to determine whether by any chance *Bacillus prodigiosus* was present. These tests proved to be in every case negative. In order to gain some idea of the length of time that *Bacillus prodigiosus* can persist in the mouth, one of us rinsed his mouth with a suspension of prodigiosus (one slant in 10 cubic centimeters of salt solution) and gargled some of the same suspension. Plates inoculated with his saliva at intervals gave the following results:

Saliva after three-fourths hour	Plate No. 1: Overgrown with prodigiosus.
Saliva after 3½ hours	Plate No. 1: Overgrown with prodigiosus.
Saliva after 5½ hours	Plate No. 1: Overgrown with prodigiosus. Plate No. 1: Overgrown with prodigiosus.
Saliva after 16 hours	Plate No. 1: 20 colonies of prodigiosus. Plate No. 2: 15 colonies of prodigiosus.
Saliva after 19½ hours	Plate No. 1: No colonies of prodigiosus. Plate No. 2: No colonies of prodigiosus.

Two meals were taken during the course of this experiment.

portion spread thinly over a second agar plate. Both plates were preserved for growth and examination. At the same time the nostrils were swabbed with a small pledget of sterile cotton moistened with salt solution and this rubbed over solidified agar. (In no case was *B. prodigiosus* obtained from the nostrils or saliva in these controls taken before spraying.)

The boys were clothed with operating gowns.

Boy No. 1 wore a Mukden mask consisting of two and one-half layers of Johnson and Johnson absorbent cotton. Thin layers of this cotton in Petri dishes were steamed in an Arnold sterilizer and then placed in the ice box so that water would condense upon the cotton and inside of the Petri dishes. A portion of the cotton thus moistened was placed in approximately the center of the mask between the layers of the cotton, so that when the mask was in place it lay before the mouth and nostrils. Small bits of the moist cotton were placed within the nostrils and a larger piece before the mouth and nostrils. This latter piece was held in place by the mask. Small pieces of dry absorbent cotton were placed on each side of the nose and then the Mukden mask was tied in place. Automobile goggles were worn over the eyes. The exposed portion of the head above the mask was covered with a cloth.

Boy No. 2 wore a Broquet mask of heavy Canton flannel cloth. This hood had been used in a number of previous experiments after each of which it had been disinfected in lysol solution and placed in the sun to dry. Small bits of the steamed moist cotton were placed loosely within the nostrils, and as in the preceding instance a larger piece of the same cotton was placed over the mouth and nostrils. This was held in place by a strip of gauze which was tied at the back of the head. A straw hat was placed on the boy's head, and the mask was then put on and tied in snugly around the neck. (See Plate V, fig. 2.)

The two boys, thus masked, were taken into a stable with the walls boarded up to keep out the light and to prevent currents of air. A suspension of prodigiosus bacilli in 0.5 per cent sodium chloride solution (1 agar slant in about 40 cubic centimeters) was sprayed by means of a throat atomizer connected with an automobile pump. The spray was directed alternately toward one mask and then the other for a period of three minutes. The boys were then brought back to the laboratory. But the gowns, goggles, and head-cloths were removed before they entered the laboratory building which was only a few meters away. This was done in order to prevent a possible contamination of the test culture plates with prodigiosus bacilli which might have become scattered in the air while the masks were being removed. (The gowns and cloths were sterilized in an autoclave at 120°C. before they were used in the next experiment.)

The subjects then proceeded to the door of the laboratory room where the masks were removed and cultures made as follows:

The cotton taken from before the mouth, that from the nostrils, and, in case of the Mukden mask, that from the interior of the mask were transferred by sterile forceps to separate Petri dishes containing solidified agar, and rubbed over the surface of the agar. Each mass of cotton was then transferred to a second Petri dish well wet with salt solution and rubbed over the second plate and left on the surface of the media.

The cotton was wet in order to afford conditions for growth to any *B. prodigiosus* which might otherwise have remained in the dry center of the cotton. (In a few cases the wet cotton mass alone, after twenty-four hours, showed the red color indicative of the growth of *B. prodigiosus*.) All plates were left in the dark at room temperature (25° to 30°C.), protected by glass jars.

The result of all the cultures, read two days later, was as follows:

Boy No. 1. Mukden mask.

Saliva taken before exposure	Plate No. 1: Prodigiosus absent.
	Plate No. 2: Prodigiosus absent.
Cotton from nostrils before exposure	Plate No. 1: Prodigiosus absent.
	Plate No. 2: Prodigiosus absent.
Cotton from nostrils after exposure	Plate No. 1: Prodigiosus *present.*
	Plate No. 2: Prodigiosus *present.*
Cotton before mouth after exposure	Plate No. 1: Prodigiosus *present.*
	Plate No. 2: Prodigiosus *present.*
Cotton within the mask after exposure	Plate No. 1: Prodigiosus *present.*
	Plate No. 2: Prodigiosus *present.*

Boy No. 2. Canton flannel Broquet mask.

Saliva taken before exposure	Plate No. 1: Prodigiosus absent.
	Plate No. 2: Prodigiosus absent.
Cotton from nostrils before exposure	Plate No. 1: Prodigiosus absent.
	Plate No. 1: Prodigiosus absent.
Cotton before mouth after exposure	Plate No. 1: Prodigiosus *present.*
	Plate No. 2: Prodigiosus *present.*
Cotton from nostrils after exposure	Plate No. 1: Prodigiosus *present.*
	Plate No. 2: Prodigiosus *present.*

A plate exposed to the air of the laboratory room, while the above plates were being prepared, showed no red colonies.

DISCUSSION OF PROTOCOL NO. 1.

This experiment shows that neither the Mukden mask nor the heavy Canton flannel Broquet mask is able to hold back completely prodigiosus bacilli when they are sprayed in large numbers continuously for a period of three minutes about the heads of the subjects. As this Broquet mask is the most efficient of all the masks with which we have experimented, it follows that none of our masks can withstand this test. The fact that the moist cotton from the center of the Mukden mask contained many prodigiosus bacilli shows that some of the prodigiosus bacilli passed directly through the mask; or, in other words, that the inefficiency of this mask is not due solely to the fact that the bacilli pass around the edges of the cotton pad or through the free spaces at the sides of the nose which were,

perhaps, only imperfectly plugged with cotton.[1] In this experiment the masks are subjected to a much more severe test than would occur in practice; nevertheless, it presents conclusive evidence, we believe, that these masks do not offer absolute protection against infection with pneumonic plague.

PROTOCOL NO. 2. (EXPERIMENTS NOS. 69 AND 70.)

February 3. A fresh culture of *B. prodigiosus* upon slanted agar was suspended in 0.5 per cent sodium chloride solution and about one-half of this suspension was sprayed through an atomizer by means of an automobile pump. The spray was directed toward all parts of a small single-roomed stable with the walls boarded up to keep out the light and, to a certain extent, the currents of air. Three minutes after the spraying had been discontinued, two subjects, one wearing our Canton flannel Broquet mask and the other a "Mukden mask" were taken into the room and allowed to remain for ten minutes. The temperature of the stable measured 28° 5 C. The weather was overcast and there had been a drizzling rain of short duration about one hour before the experiment began.

Number of living B. prodigiosus in the air.

	Time after spraying.	Number of prodigiosus colonies.
Subjects exposed.	½ to 3 minutes	Innumerable.
	3 to 6½ minutes	11,400
	6½ to 9 minutes	1,416
	9 to 12 minutes	472
	12 to 23 minutes	63

Subject No. 1. Canton flannel Broquet mask.

Saliva taken before exposure	Plate No. 1: Prodigiosus absent.
	Plate No. 1: Prodigiosus absent.
Cotton from nostrils before exposure	Plate No. 1: Prodigiosus absent.
	Plate No. 2: Prodigiosus absent.
Cotton from nostrils after exposure	Plate No. 1: Prodigiosus absent.
	Plate No. 2: Prodigiosus absent.
Cotton before mouth after exposure	Plate No. 1: Prodigiosus absent.
	Plate No. 2: Prodigiosus absent.

[1] In another experiment we obtained further evidence that bacteria may pass directly through the cotton pad of the Mukden mask. Layers of cotton as thick as the Mukden mask, sufficiently wide to cover the entire face and overlapping at the back of the head, were held in place by a many-tailed bandage, no openings in the cotton or bandage being made for the eyes. The remaining portion of the subject's head and his neck were then bandaged with layers of cotton of the same thickness and a suspension of prodigiosus bacilli was sprayed about his head for a period of seven minutes. The bacilli were recovered from the cotton immediately before his mouth and from his saliva.

Subject No. 2. Mukden mask.

Saliva taken before exposure	Plate No. 1: Prodigiosus absent. Plate No. 2: Prodigiosus absent.
Cotton from nostrils before exposure	Plate No. 1: Prodigiosus absent. Plate No. 2: Prodigiosus absent.
Cotton from nostrils after exposure	Plate No. 1: Prodigiosus *present.* Plate No. 2: Prodigiosus *present.*
Cotton before mouth after exposure	Plate No. 1: Prodigiosus *present.* Plate No. 1: Prodigiosus *present.*
Cotton within the mask after exposure	Plate No. 1: Prodigiosus absent. Plate No. 2: Prodigiosus absent.

DISCUSSION OF PROTOCOL NO. 2.

Living prodigiosus bacilli were very numerous at the beginning of the test, but decreased very rapidly during the ten minutes that the subjects were exposed. This must be regarded also as a very severe test, though by no means so severe as the preceding one. The Broquet mask withstood the tests, while the Mukden mask failed to hold back all the prodigiosus bacilli. This experiment, therefore, demonstrates clearly the superiority of the Broquet mask over the Mukden mask.

PROTOCOL NO. 3. (EXPERIMENTS NOS. 67 AND 68.)

February 1, 1912. Spraying as the preceding experiment. The two masked subjects were taken into the stable six minutes after the spraying had been discontinued and allowed to remain ten minutes. Hot, sunshiny day. Temperature in the stable 29°C.

Number of living prodigiosus bacilli in the air.

Time after spraying.	Number of prodigiosus colonies.
Subjects exposed. 1 to 3 minutes	6,000
3 to 6 minutes	2,760
6 to 9 minutes	280
9 to 12 minutes	127
12 to 15 minutes	29
15 to 30 minutes	1

Subject No. 1. Mukden mask.

Saliva taken before exposure	Plate No. 1: Prodigiosus absent. Plate No. 2: Prodigiosus absent.
Cotton from nostrils before exposure	Plate No. 1: Prodigiosus absent. Plate No. 2: Prodigiosus absent.
Cotton from nostrils after exposure	Plate No. 1: Prodigiosus absent. Plate No. 2: Prodigiosus absent.
Cotton before mouth after exposure	Plate No. 1: Prodigiosus absent. Plate No. 2: Prodigiosus *present.* (Cotton red and 32 colonies.)
Cotton within the mask after exposure	Plate No. 1: Prodigiosus absent. Plate No. 2: Prodigiosus absent.

Subject No. 2. Canton flannel Broquet mask.

Saliva taken before exposure	Plate No. 1: Prodigiosus absent. Plate No. 2: Prodigiosus absent.
Cotton from nostrils before exposure	Plate No. 1: Prodigiosus absent. Plate No. 2: Prodigiosus absent.
Cotton before mouth after exposure	Plate No. 1: Prodigiosus absent. Plate No. 2: Prodigiosus absent.
Cotton from nostrils after exposure	Plate No. 1: Prodigiosus absent. Plate No. 2: Prodigiosus absent.

DISCUSSION OF PROTOCOL NO. 3.

This test was an extremely light one. A Petri dish exposed during the first three minutes that the masked subjects were in the room developed only 280 prodigiosus colonies and another, during the last three minutes, only 29 colonies. In spite of the small number of living prodigiosus bacilli that were in the air, the Mukden mask failed to hold back all of them. We are inclined to believe that this test is even a less severe one than that to which the masks were subjected during the recent plague epidemic in Manchuria, as the coughing patients in the crowded wards must have been throwing out hundreds of fine droplets almost continuously and, on account of the low temperature, the plague bacilli in these droplets must have remained suspended in the air in a viable condition for a considerable period of time. Since we have found repeatedly in tests which were not severe that the Mukden mask allowed bacilli to pass, we are forced to the conclusion that the sense of security felt by those who wore this mask in the Manchurian epidemic was not justified.

PROTOCOL NO. 4.

This experiment was carried out in a cold-storage room measuring about 2.5 by 3 meters at a temperature of 12°C. A 24-hour agar-culture of prodigiosus was suspended in about 40 cubic centimeters of 0.5 per cent sodium chloride solution and filtered twice through cotton. A portion of this suspension was sprayed by means of a throat atomizer connected by rubber tubing with a two-cylinder force-pump such as is used in filling automobile tires. The spraying was continued for a period of two minutes, the spray being directed toward all portions of the room. The pump was then removed and the door of the cold room quickly closed. A period of two hours was allowed to elapse, and then the three masked boys were hurried into the room and the door was closed behind them. They remained ten minutes in the room. During this time each held in his hand an open Petri dish containing solidified agar and closed it immediately after leaving the cold room.

Boy No. 1 wore a Mukden mask, boy No. 2 our Canton flannel Broquet mask. The usual measures against accidental contamination with *B. prodigiosus* were adopted. Boy No. 3 wore a mask of wet gauze. Strips of

gauze were boiled and while still warm were squeezed out and applied loosely over the lower portion of the face from the eyes to below the chin. The gauze was not in layers but was placed irregularly as in surgical dressings which are intended to absorb pus. A many-tailed bandage with holes for the eyes, such as is used with the Mukden mask, pressed the moist gauze firmly against the face and held it snugly in place. This mask was about five or six centimeters thick over the mouth and became thinner toward the edges. Goggles were worn by this boy also and the top of his head was covered with a cloth reaching down to the mask.

Boy No. 1. Mukden mask.

Saliva taken before exposure	Plate No. 1: Prodigiosus absent. Plate No. 2: Prodigiosus absent.
Cotton from nostrils before exposure	Prodigiosus absent.
Cotton within mask after exposure	Plate No. 1: Prodigiosus present. Plate No. 2: Prodigiosus present.
Cotton before mouth after exposure	Plate No. 1: Prodigiosus present. Plate No. 2: Prodigiosus present.
Cotton from nostrils after exposure	Plate No. 1: Prodigiosus present. Plate No. 2: Prodigiosus present.
Plate held by boy during exposure	4,420 prodigiosus colonies.

Boy No. 2. Broquet mask.

Saliva taken before exposure	Plate No. 1: Prodigiosus absent. Plate No. 2: Prodigiosus absent.
Cotton from nostrils before exposure	Prodigiosus absent.
Cotton before mouth after exposure	Plate No. 1: Prodigiosus absent. Plate No. 2: Prodigiosus absent.
Cotton from nostrils after exposure	Plate No. 1: Prodigiosus absent. Plate No. 2: Prodigiosus absent.
Plate held by boy during exposure	4,000 prodigiosus colonies.

Boy No. 3. Mask of wet gauze.

Saliva taken before exposure	Plate No. 1: Prodigiosus absent. Plate No. 2: Prodigiosus absent.
Cotton from nostrils before exposure	Prodigiosus absent.
Cotton before mouth after exposure	Plate No. 1: Prodigiosus present. Plate No. 2: Prodigiosus present.
Cotton from nostrils after exposure	Plate No. 1: Prodigiosus present. Plate No. 2: Prodigiosus present.
Plate held by boy during exposure	4,485 prodigiosus colonies.

DISCUSSION OF PROTOCOL NO. 4.

In spite of the long interval (two hours) which elapsed between the spraying and the exposure of the subjects, this test must be regarded as a very severe one, for the plates show that numerous living prodigiosus bacilli still remained suspended in

the air at the time of the exposure. Furthermore, the number of living bacilli in the air in the cold room remains practically constant during the ten minutes of the test, while, as we have seen, in the warm stable there is a rapid decrease. This experiment shows again the superiority of our Broquet mask over the Mukden mask. It also proves that prodigiosus bacilli may pass directly through the cotton pad of the Mukden mask, for a piece of moist cotton placed near the center of the pad contained prodigiosus bacilli after the test. The mask of wet gauze also failed to hold back all the bacilli and is hence inferior to our Broquet mask. The experiment does not afford any evidence as to the relative efficiency of the Mukden mask and the mask of moist gauze.

PROTOCOL NO. 5.

March 1, 1912. The mouth of one of us was rinsed with sterile salt solution and then about 10 cubic centimeters of saliva were collected in a sterile test tube. One slant of a fresh prodigiosus culture was suspended in this saliva. The resulting suspension was thoroughly shaken and then taken a little at a time into the mouth and made into a spray by being blown between the lips. The spraying was done in a cold storage room at 9°C. The room was then kept closed for one hour, when the three masked subjects were quickly taken in and the door closed behind them. They remained inside ten minutes, each subject holding during that time an open Petri dish of solidified agar.

The masks were removed and cultures made as in the preceding experiment.

Number of living prodigiosus bacilli in the air.

	Number of prodigiosus colonies.
Plate held by subject No. 1	2,340
Plate held by subject No. 2	2,405
Plate held by subject No. 3	3,120

Subject No. 1. Mukden mask.

Saliva taken before exposure	Plate No. 1: Prodigiosus absent. Plate No. 2: Prodigiosus absent.
Cotton from nostrils before exposure	Plate No. 1: Prodigiosus absent.
Cotton from nostrils after exposure	Plate No. 1: Prodigiosus *present.* Plate No. 2: Prodigiosus *present.*
Cotton before mouth after exposure	Plate No. 1: Prodigiosus *present.* Plate No. 2: Prodigiosus *present.*
Cotton within the mask after exposure	Plate No. 1: Prodigiosus *present.* Plate No. 2: Prodigiosus *present.*
Saliva taken after exposure	Plate No. 1: Prodigiosus absent. Plate No. 2: Prodigiosus absent.

Subject No. 2. Canton flannel Broquet mask.

Saliva taken before exposure	Plate No. 1: Prodigiosus absent. Plate No. 2: Prodigiosus absent.
Cotton from nostrils before exposure	Plate No. 1: Prodigiosus absent.
Cotton from nostrils after exposure	Plate No. 1: Prodigiosus absent. Plate No. 2: Prodigiosus absent.
Cotton before mouth after exposure	Plate No. 1: Prodigiosus absent. Plate No. 2: Prodigiosus absent.
Saliva taken after exposure	Plate No. 1: Prodigiosus absent. Plate No. 2: Prodigiosus absent.

Subject No. 3. Mask of wet gauze.

Saliva taken before exposure	Plate No. 1: Prodigiosus absent. Plate No. 2: Prodigiosus absent.
Cotton from nostrils before exposure	Plate No. 1: Prodigiosus absent. Plate No. 2: Prodigiosus absent.
Cotton from nostrils after exposure	Plate No. 1: Prodigiosus absent. Plate No. 2: Prodigiosus absent.
Cotton before mouth after exposure	Plate No. 1: Prodigiosus *present.* Plate No. 2: Prodigiosus *present.*
Saliva taken after exposure	Plate No. 1: Prodigiosus absent. Plate No. 2: Prodigiosus absent.

DISCUSSION OF PROTOCOL NO. 5.

This experiment was designed to approximate more nearly to the conditions that occurred in Manchuria. It seemed possible that the viscid sputum of pneumonic plague might form larger droplets than the salt solution of our experiments and on that account be unable to pass through the masks. Preliminary tests were made by taking prodigiosus bacilli into the mouth and then holding Petri dishes containing solidified agar immediately before the mouth while talking or coughing. It was found that under these conditions prodigiosus bacilli were emitted in too small numbers and too inconstantly for the method to be satisfactory in testing our masks. Swabbing the vocal cords with the bacilli might have given satisfactory results, but this was not tried. Instead of this, it was decided to blow saliva containing prodigiosus bacilli between the lips thus converting it into a spray. The droplets of saliva produced in this way apparently passed through the masks as readily as the salt solution droplets from the atomizer. This experiment furnishes strong evidence that droplets of sputum from pneumonic-plague patients may be able to pass through the Mukden mask.

General discussion.—The protocols which have been cited could be supplemented by numerous others[8] giving similar results.

While these experiments furnish evidence that fine droplets of sputum of patients suffering from pneumonic plague may pass through the mask that was so widely used in Manchuria, yet they do not at all indicate that this mask was entirely without value. Obviously, the mask would hold back gross visible particles of sputum which are sometimes thrown out in coughing. Moreover in our experiments, when prodigiosus bacilli were recovered from the nostrils, it is probable that in the same test without the mask far greater numbers would have entered; in other words, it seems probable that great numbers of bacteria, that otherwise would have entered the nose and mouth, remain on the surface of the mask and in its substance.

Hence we believe that masks should be worn by those attending pneumonic-plague patients, but that they should not be regarded as affording absolute protection against infection; bearing this in mind, even when masked, one should remain in the near vicinity of the patient only so long as is necessary for the work in question.

CONCLUSIONS.

(1) The "Mukden mask" in general use during the epidemic of pneumonic plague in Manchuria, during the winter of 1910 to 1911, does not prevent the passage into the mouth and nostrils of *B. prodigiosus* when contained in small droplets sprayed

[8] The Mukden mask was used in 42 tests and was found to hold back the prodigiosus bacilli in only 6 of these and to allow them to pass in 36 instances. Of the 6 tests in which the bacilli failed to penetrate the mask, three were preliminary experiments to determine whether a satisfactory spray was produced in talking or coughing after rinsing the mouth with a suspension of prodigiosus bacilli; plates exposed during the experiment showed less than 20 colonies each and the method was therefore abandoned. In two others of these 6 tests the exposed plates showed only 15 and 200 colonies respectively. Finally, in the last of these 6 tests, the subject drew the cotton from before his mouth and nose into his mouth where it became saturated with saliva and plates were not made from the cotton within the nostrils.

In some of the tests in which the prodigiosus bacilli passed through the Mukden mask, the exposed plates contained only a few colonies, indicating that the test was much less severe than those in the protocols recorded above.

Our Canton flannel Broquet mask was employed in 17 different experiments. It held back all the prodigiosus bacilli in 10 of these and allowed some of them to pass in 7.

around the mask. This mask consists of a pad of absorbent cotton held over the mouth and nose by a many-tailed gauze bandage.

(2) A hood of heavy Canton flannel cloth, covering the entire head and tied in snugly at the neck, withstands much severer tests than does the Mukden mask. It does not, however, offer an absolute barrier to the passage of prodigiosus bacilli into the mouth and nostrils of the subject. This mask, with a window in front, is not more inconvenient nor more uncomfortable than the Mukden mask.

(3) It is shown that the inefficiency of the Mukden mask is not due solely to the fact that the mask fails to conform to the configuration of the face but that the bacteria may pass directly through the mask; for a piece of moist cotton placed in the center of the mask was found after the test to contain prodigiosus bacilli.

(4) It is believed that, although masks hold back many bacteria that would otherwise pass into the mouth and nostrils, nevertheless their use during the recent epidemic of pneumonic plague in Manchuria lent a *false* sense of security which may have led to the taking of unnecessary risks. We believe that these experiments fully justify the conclusion that masks such as were used in that epidemic do not offer an absolute protection against pneumonic plague.

Exhibit #4

Droplet Infection and Its Prevention by the Face Mask
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DROPLET INFECTION AND ITS PREVENTION BY THE FACE MASK

GEORGE H. WEAVER

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In recent years the spread of contagious diseases has been combated largely by measures calculated to limit the more or less direct passage or carriage of infectious materials from the sick to others. The term contact infection has often been employed to designate all such instances of direct passage or carriage, although actual contact did not always occur. Aerial transfer of infectious materials has been applied to a wide distribution of disease agents through air at considerable distances, and especially to dissemination through dust. This form of transfer has been shown to play so small a part in the spread of contagious diseases as to be practically negligible. The part played in the transfer of infections by mouth droplets driven out in forced expiratory efforts has not usually received sufficient attention. The tendency of those who have insisted on the almost exclusive rôle of contact infection in the spread of contagious diseases has been to include droplet infection among the forms of contact infection, but to assign it a minor part. The factor of distance which is a most important one has been largely ignored.

Recent experiences have served to emphasize the ease with which infections may be transferred through mouth droplets when people are brought into intimate association in military establishments. The danger of transfer in this way of secondary infecting organisms which cause most complications in cases of contagious diseases has long been appreciated by physicians who have dealt with these diseases in institutions, and they have insisted on the isolation of individuals who have active secondary infections from others who have the uncomplicated disease. Secondary infections are transferred in the same manner as the primary disease in most instances. Our recent army experiences have emphasized the fact that carriers and droplet infections are two factors which must receive a large share of attention in the management of contagious diseases.

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Intimate contact of individuals is essential in order that droplet infection may occur, and this applies equally to single persons and to larger numbers in camps, crowded cars or public gatherings within doors.

That crossed infections among patients with contagious diseases can be almost eliminated if the individuals are separated sufficiently to eliminate droplet infection and measures are taken to avoid direct carriage of infectious materials was first practically appreciated by French physicians and incorporated by them in practice in hospitals. Similar methods were soon adopted by British isolation hospitals and in this country aseptic methods in the management of contagious diseases has come into general use, largely through the consistent advocacy of Chapin and his pupils.

The droplets of mouth spray consist largely of saliva, and they are carriers of infectious materials in proportion as such are present in the mouth. Tubercle bacilli have been found in the saliva and on the tongue in a considerable proportion of cases of pulmonary tuberculosis. Diphtheria bacilli have been found on articles contaminated by saliva from persons with diphtheria. Teague[1] found diphtheria bacilli in the saliva in 77% of cases in which tonsillar cultures were positive. We have examined cultures from the tip and sides of the tongue of individuals with diphtheria and have frequently found the bacillus in this location. In any cases in which pathogenic organisms are present in pharynx, nasopharynx and in sputum from the deeper respiratory passages, it is likely that the mouth will be more or less contaminated by them and that they will be in the saliva. Many pathogenic bacteria have been found in mouth spray. Tubercle bacilli in mouth spray have been demonstrated by numerous observers, and guinea-pigs have been infected by exposure to the mouth spray of tuberculous patients.[2] In a recent study of tubercle bacilli isolated from sputum, Corper[3] says that "there is only one conclusion to be drawn from these findings as viewed from a practical standpoint, and that is that the tubercle bacilli discharged by droplet or by expectoration from open cases of pulmonary tuberculosis are a danger to mankind on direct transmission at least."

Teague[1] found that over one-half of diphtheria patients emitted diphtheria bacilli in talking and coughing, the plates being exposed for

[1] Jour. Infect. Dis., 1912, 12, p. 398.
[2] Heymann: Ztschr. f. Hyg. u. Infektionskrankh., 30, p. 139.
[3] Tr. Chicago Path. Soc., 1918, 10, p. 227.

a very short time. Hamilton,[4] in 1905, found that scarlet fever patients frequently threw out streptococci in invisible sputum. We have repeated her experiments and have found that hemolytic streptococci are often emitted in considerable numbers from the mouth of scarlet fever patients during coughing.

The occurrence of infection after exposure to mouth spray depends on several factors, especially the immunity of the individual and the number of bacteria taken in. The latter factor will vary much, and single bacteria carried to a distance would be relatively less dangerous than clumps of bacteria in heavier droplets which settle from the air before passing far from the patient. Immune individuals may, nevertheless, become carriers without exhibiting any evidence of infection. The distance to which mouth droplets are carried in the air depends principally on the force with which they are driven. Small droplets may pass some distance, especially when carried by currents of air. The observations of Doust and Lyon[5] show that the distance to which droplets are projected in quiet air is much greater than usually supposed; the "danger zone about a coughing patient has at least a 10 foot radius." Our experience would indicate that relatively few bacteria pass more than a few feet from the patient in ordinary coughing in the absence of currents of air.

Those who have studied the bacterial content of mouth spray have remarked on the great variation in the number of colonies developing after coughing toward exposed plates. This variation is partly explained by the manner of coughing. Coughing efforts which force the expired air through a relatively narrow opening produce many more colonies than do those made with the lips more widely separated. Forcible expiratory efforts carried out with the lips only slightly opened produce the most abundant droplet spray. The relative number of colonies developing after various expiratory efforts are shown in Table 1.

When the Durand Hospital of this institute was opened, rigid aseptic methods were adopted, and the nurses were specially instructed in measures calculated to protect them from infections. From March 12, 1913, to Nov. 1, 1914, nine out of 69 nurses, or 13%, acquired clinical diphtheria. From this time on, all nurses giving a positive Schick test were immunized with diphtheria antitoxin. This practically

[4] Jour. Am. Med. Assn., 1905, 44, p. 1108.
[5] Jour. Am. Med. Assn., 1918, 71, p. 1216.

eliminated active diphtheria, but from Nov. 1, 1914, to June 1, 1916, weekly throat cultures disclosed 10 diphtheria bacillus carriers among 43 nurses, or 23.25%. Up to June 1, 1916, nine cases of scarlet fever occurred among 112 nurses on duty, or in 8%.

TABLE 1

COLONIES AFTER VARIOUS EXPIRATORY EFFORTS

Showing number of colonies of Streptococcus viridans developing on blood-agar plates exposed at a distance of 1 foot during various expiratory efforts. The figures are the average of several experiments made with the same person as was employed in the experiments shown in the following tables.

Expiratory Efforts Employed	Number of Colonies
Talking (15 seconds)	1
Coughing with lips widely open (twice)	1
Whistling (15 seconds)	2
Whispering faintly (15 seconds)	4
Whispering loudly (15 seconds)	5
Blowing (twice)	50
Stuttering in a whisper (15 seconds)	55
Hawking (once)	100
Stuttering loudly (15 seconds)	100
Coughing with lips slightly parted (twice)	200
Sneezing (once)	300
Lips forced slightly apart with a puff (twice)	670

Being unable to explain so many instances of infection through faulty technic, an effort was made to eliminate a possible factor of danger which had previously been largely ignored, namely, infection through mouth spray. Since June 1, 1916,[6] gauze masks have been used by the nurses, and up to Oct. 1, 1918, 6 diphtheria bacillus carriers have been detected among 73 nurses, or in 5.2%. No case of scarlet fever has occurred since masks have been worn. The nurses are instructed to change the mask as soon as it has been known to be grossly contaminated and never to put the hands to the mask to adjust it, etc., until they have been thoroughly washed.

Early in 1918 bacteriologic tests showed that the masks we were using did not remove all the bacteria thrown out in mouth spray. The masks consisted of 2 layers of gauze, 28 by 24 mesh, but as they were worn but once before washing and resterilizing, shrinkage soon made the opening in the gauze much closer than they were in the new masks. Studies were instituted, to learn how the masks could be made most efficient.

It was assumed that the power of various gauzes to filter moist spray from air would increase with closeness of mesh and with the number of layers employed. In the first tests a spray of carbolfuchsin

[6] Our experiences up to Dec. 1, 1917, were reported in January, 1918, in the Jour. Am. Med. Assn., 1918, 70, p. 76.

was employed, the dye being susceptible of fairly accurate measurements.

A piece of cardboard 20 inches square was placed vertically on a table and an opening 4 inches square cut in it, the bottom of the opening being 4 inches from the table, and the sides equidistant from the sides of the cardboard. Back of the cardboard and opposite the opening uncovered petri dishes were placed vertically on a rack, the open side of the dish toward the opening. Toward the opening in the cardboard, with and without the interposition of gauze over the opening, a spray of carbolfuchsin was thrown by a hand atomizer. Two compressions of the bulb were used in each test and care was taken to make the compressions uniform in force. The amount of fuchsin lodging on the bottom of the dishes was determined by adding to each dish 5 c c of alcohol and pouring the alcohol with the dissolved dye into test tubes with a lumen of 1 cm. The tubes were then compared with similar tubes containing definite amounts of fuchsin dissolved in 5 c c of alcohol. In preparing the standard tubes the fuchsin lodging on a dish 6 inches from the spray with no gauze interposed was dissolved in 5 c c of alcohol and taken as 100%. The other units were made by diluting the 100% solution with alcohol. In dilutions of less than 0.1% color could not be detected.

The results of these tests are shown in Table 2.

On dishes at a distance of 4 feet from the spray the fuchsin was barely visible when dissolved in 5 c c of alcohol. The percentage of fuchsin lodging on the dishes becomes progressively less as the distance from the spray increases. The percentage of fuchsin passing through the gauze becomes less as the mesh of the gauze becomes closer and as the number of layers of gauze is multiplied.

Experiments were next made to determine how a spray of bacterial suspension would behave under conditions similar to those employed in testing the fuchsin solution. For these tests a suspension of B. prodigiosus in NaCl solution, 1 loop to 50 c c was employed. The tests were made as in the former case, except that the petri dishes contained nutrient agar. The dishes after exposure were incubated and colonies counted. The results are shown in Table 3.

It will be noted that the number of colonies became progressively less as the distance from the plates increased and also as the mesh of the gauze became finer and as the number of layers of gauze increased. It is interesting to note that at a distance of 3-5 feet from the spray the proportion of the bacteria reaching that point which passed through the gauze barriers was greater than at shorter or greater distances. This is probably to be explained by the more rapid precipitation of the larger particles as regards the nearer distances and by the failing force at the greater distances.

TABLE 2

FUCHSIN EXPERIMENTS

Showing percentage of fuchsin passing through gauze placed 3 inches from plate when sprayed as carbolfuchsin, using 2 compressions of the bulb.
The upper figures in the squares represent percentage of fuchsin as compared with the unobstructed plate at 0 inches.
The lower figures in the squares represent percentages of fuchsin as com pared with the unobstructed plate at the same distance.

Distance from Spray to Plate	No Gauze	Mesh of Gauze																					
		20 × 14				24 × 20				28 × 24				32 × 28				44 × 40			
		Layers				Layers				Layers				Layers				Layers			
		1	2	4	8	1	2	4	8	1	2	4	8	1	2	4	8	1	2	4	8
6 inches	100	40 40	30 30	5 5	0.3 0.3	40 40	10 10	2 2	0 0	30 30	5 5	0.5 0.5	0 0	30 30	3 3	0.2 0.2	0 0	10 10	1 1	0 0	0 0
1 foot	40	10 25	3 7.5	0.5 1.25	0 0	5 12.5	2 5	0.3 0.75	0 0	3 7.5	1 2.5	0 0	0 0	3 7.5	0.3 0.75	0 0	0 0	0.5 1.25	0 0	0 0	0 0
2 feet	5	0.5 10	0 0	0 0	0 0	0.3 6	0 0	0 0	0 0	0 0				0 0				0 0			
3 feet	0.5	0 0				0 0															
4 feet	0.1																				
5 feet	0.0																				

TABLE 3

B. Prodigiosus Experiments

Showing colonies developing on plates when suspension in NaCl solution of Bacillus prodigiosus is sprayed through gauze, placed 8 inches from plates, using 2 compressions of bulb.
The upper figures in the squares represent the number of colonies.
The lower figures in the squares represent the percentage of colonies as compared with the unobstructed plate at the same distance.

Distance from Spray to Plate	No Gauze	Mesh of Gauze																			
		20 × 14				24 × 20				28 × 24				32 × 28				44 × 40			
		Layers				Layers				Layers				Layers				Layers			
		1	2	4	8	1	2	4	8	1	2	4	8	1	2	4	8	1	2	4	8
6 inches	40,000	40,000 100	40,000 100	20,000 50	2,000 5	40,000 100	40,000 100	1,500 3.75	150 0.37	6,000 15	2,000 5	1,200 3	200 0.5	6,000 15	2,000 5	600 1.5	80 0.2	6,000 15	1,200 3	60 0.15	15 0.04
1 foot	20,000	20,000 100	15,000 75	10,000 50	500 2.5	20,000 100	15,000 75	500 2.5	80 0.4	1,200 6	600 3	150 0.75	200 1	1,500 7.5	5,000 25	150 0.75	300 1.5	1,200 6	200 1	50 0.25	15 0.07
2 feet	6,000	4,000 66	1,000 16.6	500 8.3	400 6.6	900 15	1,200 20	300 5	80 1.3	300 5	200 3.3	50 0.83	150 2.5	300 5	200 3.3	150 2.5	150 2.5	200 3.3	90 1.5	60 1.0	60 1.0
3 feet	1,200	800 66.6	500 41.6	300 25	250 21	500 41.6	600 50	200 16	80 6.6	100 8	80 6.6	50 4.1	100 8	300 25	100 8	100 8	150 12	200 16	80 6.6	70 5.8	50 4.1
4 feet	400	400 100	300 75	200 50	150 37.5	400 100	200 50	150 37.5	60 15	90 22.5	20 5	40 10	50 12.5	90 22.5	40 10	50 12.5	100 25	150 37.5	50 12.5	40 10	40 10
5 feet	300	300 100	100 33	70 23.3	40 13.3	80 26.6	150 50	80 26.6	25 8.3	80 26.6	24 8	40 13.3	60 20	90 30	40 13.3	50 16.6	50 16.6	20 6.6	40 13.3	1 0.3	30 10
6 feet	250	150 60	80 32	20 8	13 5.2	40 16	50 20	13 5.2	9 3.6	8 3.2	10 4	20 8	10 4	80 32	20 8	25 10	5 2	8 1.5	4 1.6	1 0.4	1 0.4
7 feet	200	150 75	100 50	20 10	7 3.5	15 7.5	20 10	6 3	1 0.5	1 0.5	2 1.0	8 4.0	4 2.0	40 20	15 7.5	3 1.5	4 2.0	0 0	3 1.5	1 0.5	1 0.5
8 feet	80	80 100	30 37.5	20 25	7 8.75	7 8.75	12 15	3 3.75	0 0	1 1.25	0 0	0 0	0 0	25 31	0 0	0 0	2 2.5	1 1.25	0 0	0 0	0 0

These results demonstrate that gauze will remove bacteria from the air when carried in a moist spray. The efficiency of the gauze as a filter is in direct ratio to the fineness of the mesh and the number of layers used.

It was now desirable to determine the efficiency of gauze of various meshes and in different number of layers as filters for mouth spray. A suitable subject for these tests was found in an adult who was the subject of a chronic antrum and ethmoid suppuration with constant purulent discharge, in whose throat and mouth abundant Streptococcus viridans were constantly present. It has been noted by those who have studied the bacteriology by mouth sprays that the number of bacteria discharged is exceedingly variable when coughing efforts are made. We found that when our subject coughed with mouth wide open few bacteria were driven out, but that an explosive cough with the lips held quite close yielded quite a rich bacterial spray. A very abundant bacterial spray was obtained by first distending the cheeks with air and then, suddenly opening the lips a little, forcing the air out with a puff. The tests were made by having the subject direct such forcible expiratory efforts toward petri dishes containing blood agar at a distance of 6 inches, the face being uncovored and covered by various gauzes in different multiples.

TABLE 4

FORCIBLE EXPIRATORY EFFORTS

Number of colonies developing on blood-agar plates which were exposed at 6 inches to two very forcible expiratory efforts in which the cheeks were first distended with air and then the lips forced slightly apart with a puff.

Number of Layers of Gauze	Mesh of Gauze									
	20 × 14		24 × 20		28 × 24		32 × 28		44 × 40	
0	2,000		2,000		2,000		2,000		2,000	
1	2,000	100%	2,000	100%	1,500	75%	1,500	75%	1,500	75%
2	1,500	75%	1,500	75%	1,500	75%	800	40%	800	40%
4	800	40%	800	40%	[illegible]	50%	500	25%	80	4%
6	500	25%	200	10%	[illegible]	2.5%	5	0.25%	0	0.0%
8	100	5%	15	0.75%	[illegible]	[illegible]	1	0.05%	0	0.0%

The results shown in Table 4 were obtained on a day when the streptococci were especially abundant. The colonies developing on the plates were practically all those of Streptococcus viridans.

It will be noted that the coarser gauze allowed a large proportion of the bacteria to pass through, even when 6 layers were superimposed. On the contrary, the finer gauzes removed many more of the bacteria, and when 6 and 8 layers were used almost all the bacteria failed to pass through. This test was rather severe, as the force used was

greater than that made in any spontaneous expiratory effort. Similar results were obtained when the pharynx and tongue had been smeared with a culture of B. prodigiosus shortly before the experiments were carried out. There appeared to be no appreciable difference between dry and moist gauze in filtering properties.

TABLE 5

STREPTOCOCCUS VIRIDANS EXPERIMENTS

Number of colonies of Streptococcus viridans developing on blood-agar plates when exposed to two explosive coughs with lips slightly parted

Distance from Mouth to Plate	No Gauze	Three Layers of Gauze 44 × 40		Colonies	Per Cent. Passing Through	Per Cent. Excluded
		Over Face	Over Plate			
6 inches	+	..	..	150		
6 inches	..	+	..	20	13.3	86.7
6 inches	..	..	+	16	10.6	89.4
1 foot	+	..	..	150		
1 foot	..	+	..	8	5.3	94.7
1 foot	..	..	+	12	8.0	92.0
2 feet	+	..	..	2		
2 feet	..	+	..	1	50.0	50.0
2 feet	..	..	+	1	50.0	50.0
3 feet	+	..	..	1		
3 feet	..	+	..	0	0.0	100.0
3 feet	..	..	+	0	0.0	100.0

Since 3 or 4 layers of gauze with a mesh of 44 by 40 removed most of the bacterial spray thrown with unusual force at a short distance, further tests were carried out to learn how efficient as filters of mouth spray 3 layers of this gauze would be when placed over the mouth of the person discharging the spray and over the exposed plate at varying distances, corresponding to the face of the person in the neighborhood. The plates were placed vertically as in the preceding experiment. The expiratory effort consisted of 2 strong coughs with the lips slightly parted. Tables 5 and 6 show the results of 2 such experiments, similar ones with slight variation being secured many times. The same person served in these tests as in the previous ones. When the gauze mask was over the face, very few colonies developed in the plates. When the gauze was over the plates the proportion of colonies as compared to unobstructed plates was also small, but slightly larger, because here the finer particles are dealt with. At a distance of 2 or 3 feet relatively more of the particles reaching that distance pass through, because here only very fine particles are projected. In the cases in which B. prodigiosus was smeared over the pharynx and tongue fewer colonies developed in plates placed behind gauze obstruction. This is probably because the bacteria were less thoroughly distributed in the

saliva. If the colonies which develop on unobstructed plates near the mouth are examined under magnification it is noticed that many are compound colonies and many of those which develop from the larger particles of saliva are the result of the growth of clumps of bacteria. Thus the number of bacteria removed is greater than the number of colonies would indicate. These larger particles of saliva are probably more dangerous not only because they contain more bacteria, but also because the toxic substances contained in the projected mucus may act on the mucous membrane where they lodge so as to favor the growth and penetration of the associated bacteria.

TABLE 6

BACILLUS PRODIGIOSUS EXPERIMENTS

Number of colonies of Bacillus prodigiosus developing on agar plates when exposed to two explosive coughs with lips slightly parted, the pharynx and tongue being previously smeared with culture of the organism.

Distance from Mouth to Plate	No Gauze	Three Layers of Gauze 44 × 40		Colonies	Per Cent. Passing Through	Per Cent. Excluded
		Over Face	Over Plate			
6 inches	+	..	..	35		
6 inches	..	+	..	0	0.0	100.0
6 inches	..	..	+	1	2.9	97.1
1 foot	+	..	..	32		
1 foot	..	+	..	1	3.1	96.9
1 foot	..	..	+	1	3.1	96.9
2 feet	+	..	..	9		
2 feet	..	+	..	2	22.2	77.8
2 feet	..	..	+	1	11.1	88.9
3 feet	+	..	..	2		
3 feet	..	+	..	1	50.0	50.0
3 feet	..	..	+	1	50.0	50.0

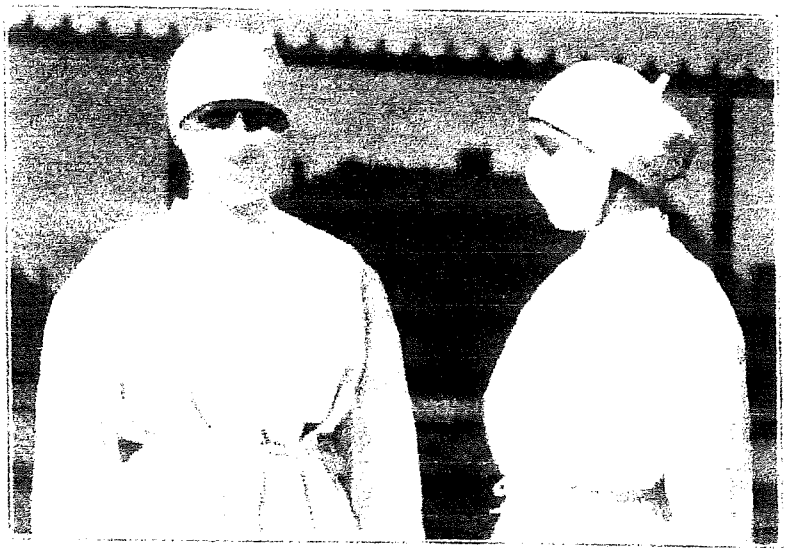
After our studies had been completed two publications of experimental studies of face masks appeared simultaneous.[7] Our results correspond closely to theirs.

Since the completion of these studies the masks used in the Durand Hospital have been made of 3 layers of gauze with a mesh of 44 by 40. The nurses are instructed to wear 2 superimposed masks, making 6 layers of gauze, when caring for cases of virulent infections when secretions are abundant. The gauze which we have used is absorbent. It is preferable to buttercloth which is treated to make the material nonabsorbent. Particles of mucus will adhere more quickly and firmly to the absorbent material as the rapid removal of the water leaves a thicker and more sticky residue. So far we have been able to secure but 1 weave of buttercloth, about 28 by 30, and this is not as fine a

[7] Haller and Colwell, and Doust and Lyon: Jour. Am. Med. Assn., 1918, 71, pp. 1213 and 1216.

mesh as is desirable. Even this is very difficult to find, most large dealers having none in stock and usually not knowing where it can be secured. In any case the dressing is removed in washing.

When the probable importance of droplet infection in the dissemination of human tuberculosis attracted attention, gauze masks to be worn by the patient were advocated. Hamilton,[4] in 1905, advised the use of gauze masks to cover the mouth of patients who had scarlet fever when there were severe streptococcal complications and when the individual could not be properly isolated. In 1916, Meltzer[8] advocated the use of a fine mesh net over the faces of patients with infantile



Directions for making the Durand Hospital Mask. Devised by Miss Charlotte Johnson, Supt.
1. Cut (44 by 40 mesh) gauze 8 inches wide and 23 inches long.
2. Turn down sides and one end ¼ inch. Fold twice, unturned end first, making 7½ inch square.
3. Cut off opposite diagonal corners 1 inch and turn in raw edge ½ inch. Stitch firmly all around.
4. Take up a 1 inch dart 1½ inches long at middle of each side of mask. Sew 14 inch tape on opposite uncut corners.
This mask has the advantage of covering the nose and mouth and in making the traction on the chin and not drawing on the nose and lips.

paralysis and also over the faces of attendants. Various mechanical protectors of the face were formerly used by physicians when swabbing throats and doing tracheotomy on cases of diphtheria. Gauze masks have been long used by many surgeons and their assistants with the purpose of protecting wounds from infection by mouth droplets.

[8] Med. Rec., New York, 1916, 90, p. 292.

Our experience with masks has been principally confined to their use to protect attendants on the sick from infection. They have been used not only by nurses, but by physicians in their work while taking cultures from throats, doing intubations and examining chests. The mask on the face interferes with putting the hands to the mouth and nose and so indirectly becomes a source of safety to the individual whose hands are apt to be contaminated in her work and who thoughtlessly may put them to the face. We have also used masks over the faces of mothers while nursing their babies when either one has been infected by diphtheria or has been a diphtheria carrier.

The employment of gauze masks over the face to prevent the transfer of infections to others was thoroughly worked out and practically applied by Capps[9] in Camp Grant. He used masks to prevent cross infections in ambulances and in the admission rooms and wards of the hospital. Similar use of masks has since been generally adopted in army and navy camps and in many civil hospitals. The intelligent use of gauze masks and other measures may be instituted equally well in private families. Many family epidemics might be limited by such means. In all instances in which infections locate in the respiratory tract and in which the infectious agent is discharged in mouth spray it is reasonable to protect those about the patient by masks of gauze. With efficient and conscientious masking, carriers of diphtheria bacilli and other pathogenic bacteria might safely be allowed a large degree of freedom.

We have noticed a considerable reduction in cases of rhinitis, tonsillitis, and pharyngitis among our nurses since masks have been worn. Endeavors to limit droplet infections should not prevent equally energetic efforts to close other channels of spread of infectious materials. The use of face masks should not give an unwarranted feeling of security to those employing them and lead to neglect of the measures which prevent carriage of infectious materials through other agents. Emphasis must still be laid on proper sterilization of eating utensils, destruction of all infectious discharges, avoiding all contamination of foods and special care regarding the washing of the hands every time the sick are handled.

CONCLUSIONS

Droplet infection comes into play whenever an individual with pathogenic organisms in the mouth gets into close contact with another

[9] Jour. Am. Med. Assn., 1918, 71, p. 448.

individual. Sneezing and suppressed coughing are most apt to produce abundant droplet spray.

Gauze will filter bacterial spray from air. Its efficiency is in direct proportion to the fineness of mesh and number of layers employed. Three layers of gauze with a mesh of 40 threads or more will remove almost all bacteria-carrying droplets. Occasional fine droplets pass through.

Gauze masks appear from clinical data to prevent infection through mouth droplets. They are useful when worn for protection by attendants on the sick, and also when worn by the infected individual to prevent contamination of his surroundings.

The use of masks should not lead to neglect of measures calculated to prevent transfer of infectious materials by other means than by droplet spray.

Exhibit #5

AN EXPERIMENTAL STUDY OF THE EFFICACY OF GAUZE FACE MASKS.

W. H. KELLOGG, M. D.,
Secretary and Executive Officer, California State Board of Health,
AND
MISS GRACE MACMILLAN,
Bacteriologist in the State Hygienic Laboratory.

Masks have not been proved efficient enough to warrant compulsory application for the checking of epidemics, according to Dr. Kellogg, who has conducted a painstaking investigation with gauzes. This investigation is scientific in character, omitting no one of the necessary factors. It ought to settle the much argued question of masks for the public. : : : : : : : : : : : : : :

THE recent epidemic of influenza brought forcibly to attention the use of the gauze mask as a protection against infection. The supposition that influenza is a droplet-borne infection suggested to many the idea of controlling its spread by requiring the wearing of face masks, and accordingly the measure was adopted in many towns and cities, principally in California. Unfortunately for the rational application of such a measure little was known of the requirements for the proper making of a gauze mask, although during the year 1918 four or five articles on the protective value of masks had appeared. One of these by Weaver* detailed his experiences in diminishing infections among the nursing staff at the Durand Hospital by the use of masks of two layers of gauze (quality not mentioned). The incidence of scarlet fever and of the carriage of diphtheria seemed to be markedly lessened, although the results are somewhat diminished in value by the fact that the experiment was not a controlled one; comparisons were made between two periods of time, during one of which the mask was used and during the other it was not. Capps* at Camp Grant tried the mask to prevent infection in ambulances and among patients while temporarily outside of cubicles. He gives no information as to the quality of gauze or number of layers and no figures or specific comparisons, and his conclusions are, that after masking, no cases of scarlet fever appeared in the wards whereas there had been just before a series of six consecutive cases. Haller and Caldwell† conducted some bacteriological experiments to determine the protective value of different layers and meshes of gauze. They found that 300 strands to the inch (the sum of the warp and the woof multiplied by the number of layers) were necessary, when worn by the person coughing in the experiment, to stop the planting of colonies on agar plates, and that 220 strands were sufficient when placed over the plate instead of over the mouth of the cougher. They gave no detailed tables of their experiments, and took no account of the possible leakage around the edge of the mask, which occurs in actual practice, nor of the influence of aspiration of droplet-laden

* Weaver, The Value of the Face Mask and Other Measures. Jour. A. M. A., Jan. 12, 1918.

* Joseph A. Capps, The Face Mask in Control of Contagious Diseases. Jour. A. M. A., March 30, 1918.

† David A. Haller and Raymond C. Caldwell, The Protective Quality of Gauze Face Masks. Jour. A. M. A., Oct. 12, 1918.

air through the gauze. Doust and Lyon* also reported on some bacteriological experiments in which they used *Bacillus prodigiosus* in the mouth of the cougher. They found that colonies passed easily through ten layers of coarse and also of medium gauze, but not through three layers of butter cloth. Their results do not agree with those of Haller and Caldwell, who found that seven layers of medium gauze "gave complete protection." Masking of plates was not reported on.

If we grant that influenza is a droplet-borne infection, it would appear that the wearing of masks was a procedure based on sound reasoning and that results should be expected from their application.

Studies made in the Department of Morbidity Statistics of the California State Board of Health did not show any influence of the mask on the spread of influenza in those cities where it was compulsorily applied, and the Board was, therefore, compelled to adopt a policy of mask encouragement, but not of mask compulsion. Masks were made compulsory only under certain circumstances of known contact with the disease and it was left to individual communities to decide whether or not the masks should be universally worn.

The reason for this apparent failure of the mask was a subject for speculation among epidemiologists, for it had long been the belief of many of us that droplet-borne infections should be easily controlled in this manner. The failure of the mask was a source of disappointment, for the first experiment in San Francisco was watched with interest with the expectation that if it proved feasible to enforce the regulation the desired result would be achieved. The reverse proved true. The masks, contrary to expectation, were worn cheerfully and universally, and also, contrary to expectation of what should follow under such circumstances, no effect on the epidemic curve was to be seen. Something was plainly wrong with our hypotheses.

We felt inclined to explain the failure of the mask by faults in its application rather than by any basic error in the theory of its use. Consequently, *Bulletin No. 31** of the Board of Health brought out the fact that where it was sought to control influenza by compulsory wearing of masks certain obstacles developed. These were:

First, the large number of improperly made masks that were used.

Second, faulty wearing of masks, which included the use of masks that were too small, the covering of only the nose or only the mouth, smoking while wearing, etc.

Third, wearing masks at improper times. When applied compulsorily masks were universally worn in public, on the streets, in automobiles, etc., where they were not needed, but where arrest would follow if not worn, and they were very generally laid aside when the wearer was no longer subject to observation by the police, such as in private offices and small gatherings of all kinds. This type of gathering with the attendant social intercourse between friends, and office associates seems to afford particular facility for the transfer of the virus. If, as seems probable, the virus is droplet-borne, this form of contact, where people are conversing with one another, would, of course, be much more dangerous than crowd association of strangers, even under the circumstances of gathering in churches and theatres. We were not satisfied, however, with this seemingly perfectly satis-

*Brewster C. Doust and Arthur Bates Lyon, Face Masks in Infection of the Respiratory Tract. Jour. A. M. A., Oct. 12, 1918.

*Influenza—A Study of Measures Adopted for the Control of the Epidemic. W. H. Kellogg, M.D.,

factory explanation. We felt it to be imperative, if the mask were not to be permanently discredited, that more definite information be obtained concerning its uses and limitations. If, as we believed, the gauze mask is useful as a protection against certain infections, it would be unfortunate if its uncontrolled application in influenza should result in prejudicing critical and scientific minds against it. That there was danger of this is evidenced by many letters received from prominent sanitarians all over the country. It was, therefore, determined to carry out a set of experiments that should demonstrate finally just what type of mask should be used against droplet-borne infections, and what measure of protection could be expected through their use.

It is the object of this paper to set forth these experiments, and it is believed that they are fairly complete, so far as it is possible by laboratory methods alone to arrive at a conclusion. It will remain for future controlled experiments in contagious disease hospitals to dispose of such questions as conjunctival entry of virus, hand infection, etc.

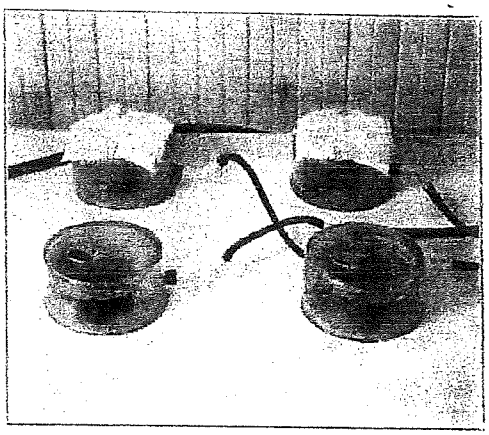
All previous laboratory experiments with which we are familiar have overlooked certain conditions in the practical application of masks which might have an important bearing on the true facts. It occurred to us that the mere settling by gravity of micro-organisms through layers of gauze stretched over petri plates did not simulate at all the natural conditions of forcible aspiration through the gauze that obtains during inhalation by a masked individual.

Another possible source of error which it was desired to investigate was the possibility of droplet laden air passing around the edges of a mask and then entering the nostrils without filtration. A long series of preliminary experiments was necessary, much of which will be passed over without description as being of little interest, although of extreme importance as a foundation for the later decisive operations.

The first procedure that occurred to us, as it has to others, was the inoculation of plates, both covered with gauze and uncovered, by coughing over them at various distances. It was soon determined that an artificial enrichment of the secretions was necessary, and this was secured by spraying the mouth and throat of the cougher with a suspension of *Bacillus prodigiosus*. It was also decided, after many tests, to abandon the inoculation by coughing, as it was found that no degree of uniformity could be maintained. The counts varied enormously from one moment to another. Consequently, controls were rendered of less value and an undesirable variation was shown between individual experiments.

For the purpose of imitating, as closely as possible, natural conditions of forcible suction through the gauze, an arrangement was constructed from a glass dish 2½ inches deep and 4¾ inches in diameter with ground edges and having for a cover a glass plate having a round groove ground on one face to fit tightly the edge

FIGURE 1.



of the dish. In use, this cover, sealed on with paraffine, served as the bottom of the apparatus, and a 1½-inch hole was bored through the bottom, now the top, of the covered dish. (See Fig. 1.) A small hole, one-half inch in diameter, was bored through the side of the dish for the attachment of a suction tube. Petri plates were placed, uncovered, inside this jar and supported on large corks, which are plainly shown in the illustration, opposite the large hole which could be masked or not, as desired.

In the earlier experiments straight and curved funnels for the attachment of gauze masks were inserted in the large opening of these jars, but later these were abandoned and the gauze placed directly over the opening in the jar. In the use of these funnels, which are shown attached to the jar in Fig. 2, it was noted that there is a great diminution in the number of bacteria passing through them on the gentle suction current as compared to the number entering directly through the hole over the open plate. The reduction was more marked with the curved funnel than with the straight one, suggesting that possibly a tube with several bends would, if breathed through, check the passage of bacteria as well as a close gauze filter.

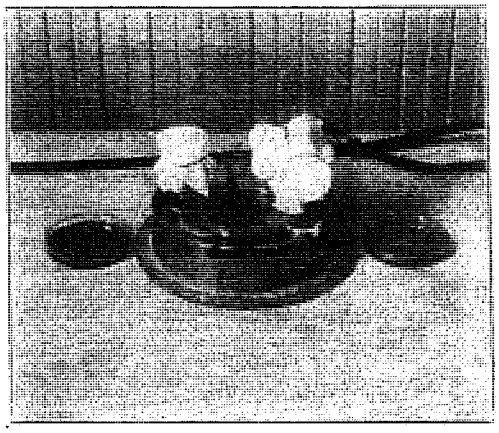
EXPERIMENT NO. I.

First set. No mask on cougher.

Location of plate	Colonies, 48 hours room temperature
Inside jar under straight funnel	21
Inside jar under curved funnel	5
Outside front	137
Outside right side	98
Outside left side	47
Outside back	79
Second set. Cougher masked.	
Inside jar under straight funnel	9
Inside jar under curved funnel	3
Outside front	11
Outside right side	16
Outside left side	11
Outside back	19

The preceding table is an example of the results obtained with the apparatus placed four feet in front of the cougher, who was masked with six layers of 40 by 17 mesh gauze in one experiment and not masked in the other. Besides one plate under each funnel, a curved and a straight one, which were not masked, four plates were placed entirely outside in a vertical

FIGURE 2.



position, one in front of, one behind, and one on each side of the jar.

After numerous other experiments, it was decided that the coughing process was too variable and uncertain, and various types of atomizers were tried, both with compressed air with various pressures and with the ordinary rubber bulb. Example of results:

EXPERIMENT NO. II.

DeVilbiss atomizer No. 15.

Saline suspension of 48-hour culture of *Bacillus prodigiosus*.

Plates in jars.

Vacuum pump, attached to jars instead of having assistant inhale through the tube as previously done.

	Distance from atomizer		
	1 ft.	2 ft.	3 ft.
Without mask	5,280	31	0
Mask, 6 layers, 20 by 17	1,380	20	..

In the following experiment a suspension of *B. prodigiosus* in light paraffine oil was used in attempting to get more uniform counts in the controls, which, with the use of saline spray, were frequently too thickly planted to be easily counted:

EXPERIMENT NO. III.

Mask made of gauze having 20 woof and 17 warp threads to the square inch—6 layers.
Atomizer—DeVilbiss No. 15.
Pressure—From compressed air pipe, about 40 pounds pressure.
Culture—*B. prodigiosus* 48-hour growth suspended in paraffine oil, sprayed at plates for 30 seconds allowing 4½ minutes for the droplets to settle.
Incubation—24 hours, 37° C.

	Distance from atomizer					
	3 ft.	4 ft.	5 ft.	6 ft.	7 ft.	8 ft.
No mask	12,000*	10,000*	6,756	4,548	3,372	3,126
Mask, 6 layers..	1,560	1,050	816	562	426	384
Mask, 5 layers..	1,314	1,248	624	222	282	174
Mask, 4 layers..	5,596	2,976	1,692	1,290	846	576
Mask, 3 layers..	10,500	7,300	4,248	3,504	2,472	1,378

* Number estimated.

Many details of these experiments are unrecorded in this article as being of little interest, essential facts only being presented.

As illustrating these omissions we would mention a long series of experiments to find the proper air pressure to use and the time of exposure, and those experiments leading up to the rejection of atomizers of the nebulizing type, such as DeVilbiss No. 49. As an illustration one of the final experiments for determining distances and pressure is given.

EXPERIMENT NO. IV.

Filtered oil suspension of 48-hour culture of *B. prodigiosus*.
Pressure—43 pounds.
Atomizer—DeVilbiss No. 15.
Time—just turning on and off, allowing 5 minutes for settling.
Spray comparable to a sneeze.
Suction pump attached to each jar during spray and settling time.
Rate of suction gauged to correspond as nearly as possible to normal rate of inspiration.
No gauze over opening in jar.

	Distance from atomizer		
	3 ft.	4 ft.	5 ft.
Plates outside jar	2,676	2,704	2,976
Plates inside jar	663	831	1,260

EXPERIMENT NO. V.

Same as Experiment No. IV, but with gauze having a mesh of 24 by 18 threads to the square inch over the inlet to the jars.
Number of layers—6.
Distance from atomizer—5 feet.

	Colonies
Control plates outside of suction jars	4,764
Control plates inside jars, no gauze	2,468
2 layers of gauze	1,830
3 layers of gauze	1,280
4 layers of gauze	544
5 layers of gauze	674
6 layers of gauze	360
7 layers of gauze	454
8 layers of gauze	63
9 layers of gauze	42

EXPERIMENT NO. VI.

Same as preceding, but allowing exposure of three minutes instead of five.

Distance from atomizer—4 feet	Colonies
Control plates outside of suction jars	2,694
Control plates inside of suction jars	409
2 layers of gauze	358
3 layers of gauze	420
4 layers of gauze	344
5 layers of gauze	338
6 layers of gauze	294
7 layers of gauze	184
8 layers of gauze	167

EXPERIMENT NO. VII.

Filtered oil suspension—48-hour culture of *B. prodigiosus*.
Pressure—43 pounds.
Atomizer—DeVilbiss No. 15.
Time—Just turning cock on and off allowing 5 minutes for settling.
Suction—25 pounds on jars during spray and time for settling.
Gauze—42 by 44 threads to the square inch.

	Distance from atomizer	
	4 ft.	5½ ft.
No gauze	366	421
Outside plates (no suction)	4,400	5,280
2 layers of gauze	329	684
3 layers of gauze	391	699
4 layers of gauze	251	372
5 layers of gauze	114	264
6 layers of gauze	12	22
7 layers of gauze	4	7
8 layers of gauze	5	4
9 layers of gauze	9	13

EXPERIMENT NO. VIII.

Same as preceding, but allowing three minutes for settling instead of five.

	Distance from atomizer	
	4 ft.	5½ ft.
No gauze	211	127
Outside plates (no suction)	3,594	1,836
2 layers of gauze	50	20
3 layers of gauze	20	8
4 layers of gauze	20	18
5 layers of gauze	25	13
6 layers of gauze	0	0
7 layers of gauze	0	1
8 layers of gauze	0	0
9 layers of gauze	1	0

EXPERIMENT NO. IX.

Filtered oil suspension—48-hour culture of *B. prodigiosus*.

Pressure—43 pounds.

Atomizer—DeVilbiss No. 15.

Time—Just turning cock on and off, allowing 5 minutes for settling.

Suction on jars during spray and time for settling.

Gauze—60 by 72 threads to square inch.

	Distance from atomizer	
	4 ft.	5½ ft.
No gauze	871	172
Outside plates (no suction)	4,572	5,724
1 layer of gauze	1,771	1,110
2 layers of gauze	897	250
3 layers of gauze	133	127
4 layers of gauze	26	12
5 layers of gauze	18	14
6 layers of gauze	35	7
7 layers of gauze	21	6
8 layers of gauze	25	8
9 layers of gauze	17	4

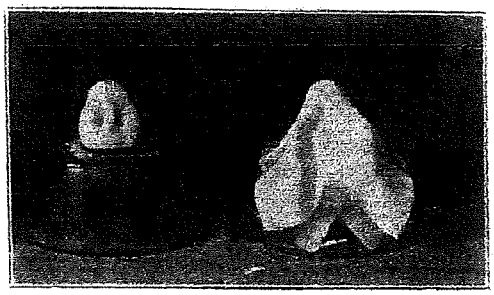
It was noted from a study of experiments V and VI that gauze of medium texture, namely 24 by 28 threads, has no notable restraining effect up to eight layers, agreeing with Doust and Lyon's experience that ten layers of medium gauze were penetrated in their coughing experiments. Experiments VII, VIII and IX are of more importance as they deal with fine and extra fine gauze (butter cloth). Haller and Caldwell found that a total of 220 strands (warp plus woof times layers) to the inch practically stopped the passage of organisms when applied over petri plates, and Doust and Lyon concluded that three layers of butter cloth would filter *B. prodigiosus*. They do not give the mesh of this butter cloth, but presumably it corresponded to the 42 by 44 thread gauze in our experiments Nos. VII and VIII, in which we found that with the element of aspiration introduced, as in the natural use of masks, even five layers did not give a sufficient reduction in count to make such a mask of value. Furthermore, our experiment No. IX in which the very best and finest cloth of 60 by 72 strands to the inch was used, demonstrated that under the natural conditions of aspiration of droplet-laden air through the mask, four layers, which would be extremely difficult to breathe through, are required to obtain a degree of filtration which would hold out any hope of useful result in practice.

The following series of experiments were to determine the possibility of the passage of droplet-laden air around the edges of a close mask instead of through it, and also to simulate other physical conditions attending the wearing of the mask. In these experiments artificial noses of paraffine were made for the purpose of securing the closest approach possible to the natural physical conditions of the wearing of masks by persons.

Figure 3 illustrates these artificial noses which are attached to the glass jars, within which are placed the petri plates immediately behind the passages through the paraffine.

Various combinations with the models

FIGURE 3.



were tried. In experiment No. X a nose without nostrils was used in addition to the regular one, for the purpose of establishing the leakage around the edges of the mask. The tabulation of results shows the restraining influence of the nasal passages as the counts are larger where the air passes directly into the aspiration jar instead of by way of the nasal passage. Another outstanding feature of this test is that there is little difference in results obtained with different layers within the range of the number that would be acceptable from a standpoint of comfort.

Experiment No. XI (see Fig. 4 and Table I), was conducted with different types of gauze and varying numbers of layers. An inspection of the table of results in Set 1 shows that an increase of efficiency was noted with the increase of the number of layers and that the results were better in column C where the air was required to pass through the mask and no opportunity existed for passing around the edges, as was the case in column A where the mask was placed over the nose. The difference, however, was not very material showing that the

EXPERIMENT NO. X.

Filtered oil suspension—48-hour culture of *B. prodigiosus*.
Pressure—43 pounds.
Atomizer—DeVilbiss No. 15.
Time—Just turning cock on and off allowing 3 minutes for settling.
Suction during spray and time for settling.
Gauze—60 by 72 threads to the square inch.
Large jar—two holes—one covered by wax nose with nostrils; other open with wax nose without nostrils just above hole.
Distance from atomizer—5 feet.
Jar standing vertically.

Layers of gauze	No nostrils	Nostrils
No gauze	762	150
Outside plate	2,630	
5 layers	54	15
6 layers	81	20
7 layers	35	13
8 layers	18	15
9 layers	12	9 patch
10 layers	3	8

EXPERIMENT NO. XI.

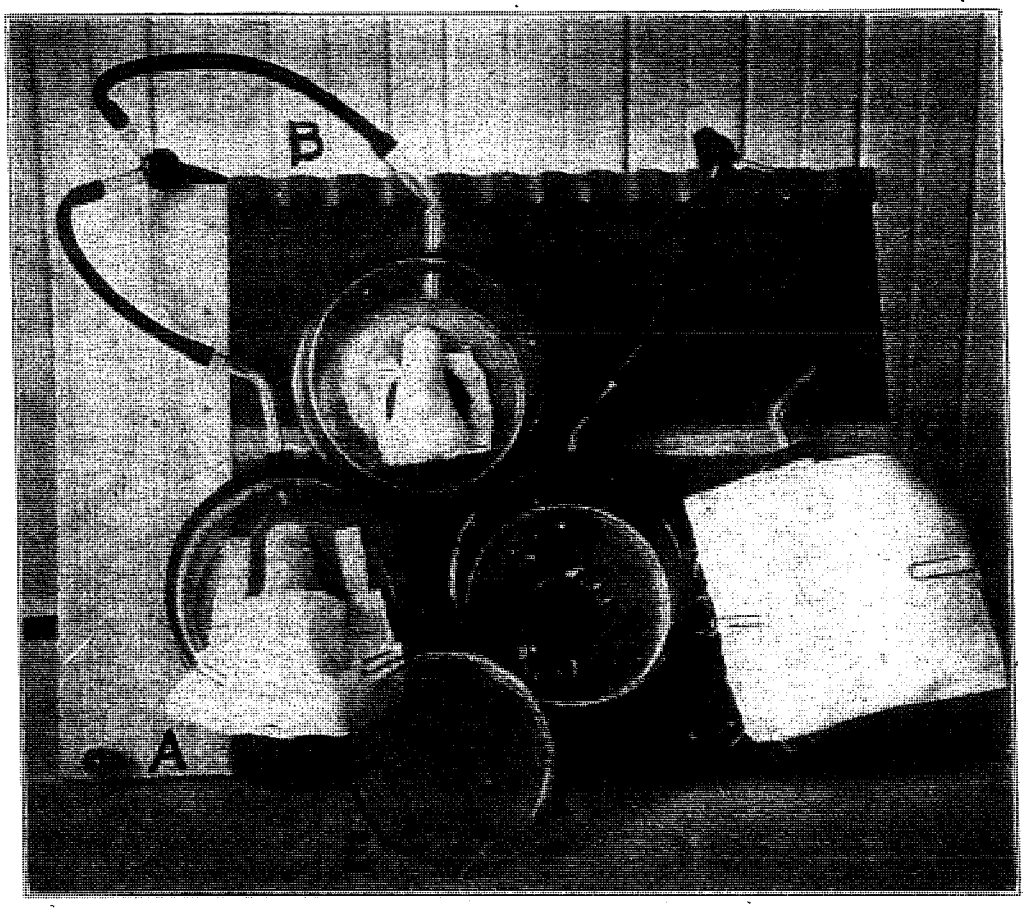
Filtered oil suspension—48-hour culture of *B. prodigiosus*.
Pressure—43 pounds.
Atomizer—DeVilbiss No. 15.
Time—Just turning cock on and off allowing three minutes for settling.
Gauze—60 by 72 threads to the square inch in Set 1 and 24 by 28 in Set 2.
Distance from atomizer—5 feet.
Suction on all jars during spray and time for settling.
All jars standing vertically.

TABLE I

EXPERIMENT No. XI.

	A	B		C	D		E
	Masked nose	Unmasked nose	Per cent of Efficiency	Gauze over jar—no leakage around edges	Open plate	Per cent of Efficiency	Outside of jar
Set 1—Gauze 60 x 72 threads to square inch.							
9 layers of gauze	0	10	100	0	200	100	1,000
8 layers of gauze	1	56	98	1	73	98.7	1,122
7 layers of gauze	37	160	77	64	183	70	1,265
6 layers of gauze	35	154	77	5	117	95	1,230
5 layers of gauze	127	300	57	109	407	70	1,260
Set 2—Gauze 24 x 28 threads to square inch.							
10 layers of gauze	39	654	94	34	992	96	1,776
9 layers of gauze	42	790	94	240	1,716	86	1,980
8 layers of gauze	patches						
8 layers of gauze	296	681	56	190	684	72	2,042
7 layers of gauze	450	1,980	77	189	1,440	86	Too many to count
6 layers of gauze	666	1,089	38	466	695	32	2,690

FIGURE 4.



A. Hole in top of jar covered by wax nose with nostrils and gauze mask.
B. Hole in top of jar covered by wax nose with nostrils. No mask.
C. Hole in top of jar covered by gauze mask attached by adhesive.
D. Hole in top of jar, not covered.
E. Plate outside of jar—no mask.

principal source of lack of efficiency is in the forceful aspiration of air through the mask. This table also shows that five layers of this extremely fine gauze, which would be impossible of comfortable use, gave an efficiency of only 57 per cent.

CONCLUSIONS.

1. Gauze masks exercise a certain amount of restraining influence on the number of bacteria-laden droplets possible of inhalation.

2. This influence is modified by the number of layers and fineness of mesh of the gauze.

3. When a sufficient degree of density in the mask is used to exercise a useful filtering influence, breathing is difficult and leakage takes place around the edge of the mask.

4. This leakage around the edges of the mask and the forcible aspiration of droplet laden air through the mask is sufficient to make the possible reduction in dosage of infection not more than 50 per cent effective.

5. It remains for future controlled experiments in contagious disease hospitals to determine whether the wearing of masks of such texture as to be reasonably comfortable are effective in diminishing the incidence of infection.

6. Masks have not been demonstrated to have a degree of efficiency that would warrant their compulsory application for the checking of epidemics.

A STUDY OF THE TOXICITY OF DIPHTHERIA BACILLI ISOLATED FROM IMMEDIATE CONTACTS.

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Health Department, Baltimore, Md.

The members of the community at large are not often sources of diphtheria infection and we must look elsewhere to find the factors of greatest danger. School children do not furnish the source of infection. These investigators point to convalescents and contacts as being the probable distributors of the virulent bacilli. : : : : :

THE relation of the carrier of the diphtheria bacillus to the spread of this disease has been the object of much research, and the percentage of true diphtheria bacilli, both from the standpoint of morphology and of virulence has been determined in several distinct groups of the population.

The percentage of morphologically true diphtheria bacilli has been studied by the Massachusetts State Board of Health,[1] which found that 3 per cent of persons not known to have been exposed to infection harbored morphologically true diphtheria bacilli, while the organisms were present in from 8 to 50 per cent of those exposed to diphtheria. Park[2] found that 9.7 per cent of 330 healthy persons showed morphological diphtheria bacilli but only 2 per cent of these were virulent.

The percentage of persons in the general population harboring morphologically true diphtheria bacilli (classified according to Westbrook's types) was also studied by Goldberger, Williams and Hachtel[3] during the winter of 1913 and 1914 in Detroit. For nearly a year prior to the commencement of this investigation diphtheria had been unusually prevalent in Detroit, but the percentage of cases markedly decreased about three weeks before the collection of cultures began, so that the investigation really resolved itself into a study of the diphtheria carriers at large in a typical population shortly after a time of increased prevalence of the disease. They made cultures from a representative portion of the population, cultures from the nose and throat of 4,093 healthy persons being examined; 38, or 0.928 per cent, were found to harbor morphologically true diphtheria bacilli. Nineteen pure cultures of the diphtheria bacillus were isolated and 2 of these were found to be

Exhibit #6

of milk, eggs, cocoa, etc., to the dietary, or by supplementing this with some readily assimilable carbohydrate as, for example, lactose in a beverage.

22. For the roentgen examination of old cavities with fistulas, we have found thorium nitrate in 10 and 15 per cent. solutions to be of value. Its advantages over pastes of various kinds are its ease of introduction and of withdrawal. A 20 per cent. aqueous solution of potassium iodid appears to give results about equivalent to those secured with the solution of thorium, and is more easily obtained and less expensive. Like thorium nitrate, it is distinctly though mildly irritating.

23. The increased expansion of the lung following the use of Dakin's solution leads to the hope that extensive intrathoracic operations, such as decortication of the lung, may in most cases prove unnecessary. Such procedures should be undertaken only after most prolonged efforts to obtain expansion of the lung have failed, and then only when the surgeon has at his command every facility in the shape of intratracheal anesthesia, assistants and armamentarium.

MEASURES FOR THE PREVENTION AND CONTROL OF RESPIRATORY INFECTIONS IN MILITARY CAMPS*

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The two great surprises of the last year in the Army camps have been, first, the rarity of gastro-intestinal infections, and, secondly, the frequency of respiratory infections, particularly of the streptococcus group.

In former wars, infections of the alimentary tract, such as typhoid and dysentery, were responsible for the great epidemics. In our training camps of today, typhoid and paratyphoid are curiosities and dysentery is an exceptional occurrence. The disappearance of this formidable group of diseases can be attributed in part to the general use of typhoid inoculation and in large measure to the safeguarding of the drinking water from contamination.

During the Spanish-American War the danger arising from polluted water was well known, but careful and comprehensive methods of protection were not carried out. Today an army camp digs its own wells, builds reservoirs, subjects the water to frequent bacteriologic examinations, and in other ways rigidly and scientifically applies the knowledge gained by previous failure. No expense is too lavish, no effort too great, to provide this insurance of soldiers against waterborne infections. And the results abundantly justify the expenditure.

Are we employing equally rational and efficient methods in our efforts to control respiratory infections? Are we not neglecting to apply certain preventive measures that are logically suggested by our knowledge of their etiology and of their modes of dissemination?

MILK AS A CARRIER OF STREPTOCOCCI

Infected milk, cream and ice cream may be playing a rôle in the causation of respiratory infections, especially those due to the streptococcus, somewhat similar to that of contaminated water in the causation of gastro-intestinal diseases. That virulent streptococci flourish in milk is well known. The epidemics of streptococcus sore throat in recent years in Boston, Chicago, Baltimore and many smaller cities, traced as they were to contaminated milk, fully demonstrate that milk must always be reckoned with as a potential cause of any streptococcus outbreak. Even ice cream may preserve these germs in a virulent form for several weeks. Milk is capable also of carrying the germs of scarlet fever, diphtheria and perhaps of other contagious respiratory diseases.

During last winter a sharp epidemic of septic sore throat at Camp Grant was attributed, with a high degree of probability, to the milk. Following these cases came a wave of scarlet fever. Both of these diseases decreased when the milk was boiled.

The prevalence of streptococcus infection, both primary and secondary, has been remarkable in all the camps. It is not far from the truth to say that the streptococcus has been responsible for more deaths than all other organisms combined. Sore throat, bronchitis, sinusitis, pleurisy, bronchopneumonia and pericarditis, have been the more common manifestations. Of course, the contagion spreads from one person to another, but it is quite possible that a fresh stream of streptococci is constantly flowing into the camp and being disseminated by milk, cream and ice cream. A comprehensive and exhaustive study of this whole subject by competent investigators is imperatively needed at the present time.

In the meantime, however, in view of the constant danger of contamination, all milk and cream products should be pasteurized under direct supervision of the camp authorities. The most satisfactory and reliable means of accomplishing this end is to build and equip a pasteurizing plant in the camp proper, and have the process carried out and supervised by Army men. Such a plant could also manufacture all the ice cream used at messes and canteens.

Thorough pasteurization of milk in its various forms might reasonably be expected greatly to cut down the incidence of streptococcus infections and possibly that of scarlet fever and diphtheria.

ISOLATION OF SOLDIERS BY MEANS OF THE FACE MASK

As previously stated, most of the diseases encountered in the training camps are infections of the respiratory tract such as meningitis, diphtheria, scarlet fever, mumps, measles, German measles, pneumonia, whooping cough, streptococcus tonsillitis, bronchitis and bronchopneumonia. All of these communicable diseases are transmitted from one individual to another by means of the secretions of the nose and throat. Talking, coughing and sneezing force a fine spray of mucus and bacteria into the air which may directly infect another person and which contaminates clothes, bedding and furniture.

Crowding in barracks, at the mess table, and in recreation rooms facilitates the transmission of these infections and explains their rapid spread in Army camps. Crowding in the ambulance, in the receiving office and in the wards is even more favorable to germ transmision, because a large proportion of these soldiers are already affected with some contagion, and they simultaneously expose themselves and their comrades to a secondary infection.

* Read before the Section on Practice of Medicine at the Sixty-Ninth Annual Session of the American Medical Association, Chicago, June, 1918

The remedy for crowding is group separation and, as far as possible, individual isolation. The segregation of newly arrived troops for three weeks in detention camps is one of the most vital measures in checking contagion.

The expedients of increasing the space between beds in barracks, of placing the head of one soldier opposite the feet of his neighbor, of stretching tent flaps between beds, and of suspending a curtain down the center of the mess table, are all of proved value. But the most efficient method for securing isolation of the individual is the use of a face mask, made with three or four layers of gauze in the shape of a rectangle measuring 5 by 7 inches.[1] The mask has long been employed by surgeons as a filter for the expired air in the operating room. It has been used successfully at the Durand Hospital by Weaver[2] for the protection of physicians and nurses engaged in the care of patients with contagious disease.

So far as we can learn, however, the use of the face mask for patients had never been practiced. In a hospital where each patient is confined to a separate room, there is no reason for masking the patients. But in hospital wards where, even with cubicles, patients must mingle and expose one another to respiratory infections, the face masks on theoretical grounds promised protection.

The experiment was started at Camp Grant[3] in the latter part of January, 1918, and was so successful that it was instituted as a routine measure in most of the medical wards early in February.

The system is carried out (1) at the regimental infirmary, (2) in the ambulance, (3) in the receiving office, and (4) in the wards. The directions observed are as follows:

1. At the regimental infirmary every patient with contagious disease is masked immediately after the diagnosis is made.

2. Every patient on entering the ambulance, whether infected or clean, is masked. Each ambulance carries a box of clean masks, which is replenished at the receiving ward.

3. At the receiving office the ambulance patients continue to wear their masks. Other patients who walk to the hospital for minor ailments are masked at the door by a noncommissioned officer. All retain the mask in place during the examination and on the trip to the ward, and remove it only when they are in the ward cubicles. Since the initiation of this practice, the occurrence of cross-infection from contact in ambulance and receiving ward, previously quite frequent, has been rarely observed.

4. In all wards for contagious and respiratory diseases (this includes nearly all the medical wards) the mask is worn by patients as well as by physicians, nurses, ward men and visitors. As long as the patient remains within the shelter of the cubicle he need not wear the mask, but he puts it on whenever he leaves the cubicle for any reason. Patients must either have their meals served in bed or while masked procure their tray of food and carry it to the cubicle. All eating utensils are sterilized after each meal.

Smoking is absolutely prohibited, as it necessitates the removal of the mask.

In view of the danger of transmission from the wash bowls, the plugs are removed, so that only running water is available for washing the face and teeth. Only one person at a time is allowed in the wash room, as the mask is necessarily removed therein. On the other hand, there is no objection to several persons occupying the latrine at the same time. The latrine is kept separated from the wash room in the double wards by locking the communicating door, in the single wards by hanging up sheets between closets and wash basins. To enforce the wash room regulations, a guard, who is usually a convalescent patient, sits outside the door.

Much depends on stimulating a lively interest in the scheme on the part of nurses and ward men. The ward surgeon very easily wins the cooperation of the patients themselves by frequent short talks, explaining the purpose of the masks and pointing out their similarity to the gas masks.

From February 1 to June 1, 1918, the cubicle and mask were in continuous operation. Whenever a case of scarlet fever broke out the ward was placed in quarantine for one week; when measles broke out, the ward was quarantined for two weeks.

In twenty wards exposed to scarlet fever as a secondary infection, only one subsequent case of scarlet fever developed during the week of quarantine.

In eight wards exposed to measles as a secondary infection, not a single case of measles developed during the two weeks of quarantine.

The system may be said to have been efficient in 95 per cent. of the exposures to scarlet fever and in 100 per cent. of the exposures to measles.

If this experience can be taken as a criterion, we soon shall be justified in ignoring the quarantine of the ward in these cross-infections, provided the system of masking and the cubicle is in good working order at the time of their appearance.

1. Commercial gauze varies greatly in weight and closeness of weave, so that it is important to fix a standard texture and the number of layers required to afford protection. Major Haller, chief of the laboratory at this hospital, is completing bacteriologic experiments for this determination and will publish his results in an early number of THE JOURNAL.

2. Weaver, G. H.: The Value of the Face Mask and Other Measures in Prevention of Diphtheria, Meningitis, Pneumonia, etc., THE JOURNAL A. M. A., Jan. 12, 1918, p. 76.

3. Capps, J. A.: A New Adaptation of the Face Mask in Control of Contagious Disease, THE JOURNAL A. M. A., March 30, 1918, p. 910.

ABSTRACT OF DISCUSSION

DR. JAMES S. MCLESTER, Birmingham, Ala.: We have used the method suggested by Dr. Capps at Camp Sheridan with satisfactory results. At one time in the measles ward almost every patient had coryza or bronchitis, and bronchopneumonia was developing rapidly. We removed every case of bronchopneumonia as soon as recognized, but that did not stop the spread. Finally, we put all the beds in that ward in cubicles and washed all the patients. Very soon the bronchopneumonia ceased to appear. That was to me a graphic demonstration of the value of the mask and of the cubicle system of isolation. Later on we had a similar experience in an epidemic of so-called grip. This disease spread rapidly through the hospital. Finally we made universal use of the mask and the cubicle and were thus able effectually to control the epidemic.

DR. JOHN A. LICHTY, Pittsburgh: In a large civilian hospital during the past winter our experience was much like that of Major Miller and Major Stone. We had two epidemics of pneumonia in the Mercy Hospital at Pittsburgh. The first epidemic came early in the winter and seems to have occurred mostly in colored men who had come from the South in the summer and who had never lived in the North. They came poorly clad and were improperly housed. They did not use the large wages they received to feed themselves properly. These men had a typical lobar pneumonia. They came into the hospital late, usually on the seventh day; and the mor-

tality was very high. We did not have time to group them all or to treat them with the serum after they were grouped because they died so soon after entering the hospital. The other group came in the latter part of the winter when the cold weather began to break up. This was an entirely different class, and it corresponded with the class of pneumonia which seems to have occurred in the camps where there were abscesses of the lungs, empyema, etc., because they were very irregular, they were hard to diagnose, and, no matter whether they came in early or late, the cases were almost invariably fatal.

There should be propaganda work with reference to pneumonia just as there is with cancer. The laity should know what the early symptoms of pneumonia are, or the laity should be as keen about pneumonia as they are about appendicitis. Then, I believe, we can do much more with serum treatment than we have done heretofore.

DR. H. P. GREELEY, Madison, Wis.: This symposium has brought out the fact that pneumonia is, first and foremost, an upper respiratory tract disease. The question which I want to ask is, In what proportion of cases in the epidemics at the cantonments was the upper respiratory tract the seat of an acute inflammation? Dr. Capps has shown conclusively the value of masking in the prevention of pneumonia. Is local treatment of value in the preliminary stage of upper respiratory tract inflammation, the stage of invasion? Can any antiseptic local treatment be employed as a prophylactic?

DR. ALBERT R. TRAPP, Springfield, Ill.: I have often observed infected teeth and tonsils antecedent to pneumonia. These chronic infections increase the susceptibility and decrease the resistance to pneumonia. In treatment it would seem wise to combat these infections. Another thing I should like to have seen taken up is the viscosity of the blood. Wright has spoken of the citrates as diminishing the viscosity of the blood. It would seem that this could be tried out.

DR. CHARLES N. LOVEWELL, Fort Snelling, Minn.: I have had somewhat the same experience at Snelling as you did at the other camps. We are located near the University of Minnesota, and one of the things I have been grateful for since coming into the service is the fact that we were so assigned. The men there have been exceedingly kind to us in confirming some of our work, and because of the help they have given us we have been able to do better work than we otherwise could have done. In our work on pneumonia we have been able to classify the cases according to types. We had a comfortable, satisfactory time with our pneumonias in October, November and December. About the 1st of February troops from Kelly Field were sent to us, and then our troubles began, for with them came a type of pulmonary disease I had seldom seen before. Major Miller spoke about the great variance in the physical findings. It filled me with a great deal of satisfaction and, I declare, I felt better when I realized that others, and men of skill and ability, should be annoyed by the difficulties presented in arriving at correct diagnoses from their physical signs. We found every variety of physical sign disproved at necropsy. We found apparent empyema disproved by the surgeon going in and finding no empyema there. The pleuritis due to streptococci was associated with an exudate of gelatinous material which we have examined at necropsy and found by squeezing to be full of pus, although it would appear to be free from fluid. We have at the present time in our hospital fifteen cases of streptococcic pneumonia followed by empyema. Some of them, over half of them, have been in the hospital since March 1. Among the patients that are not there now, some having been discharged and some having gone to Fort Bayard, we have noted quite a large percentage of cases developing tuberculosis. I have not heard that mentioned here this morning. There is another thing that impressed me very much, and that was the apparently almost simultaneous occurrence of suppurative peritonitis with empyema, simulating appendicitis and pneumonia at the same time. We have made the mistake of operating in one of these cases, in which we found that condition. We have had some patients die of severe toxemia within an hour of their admission to hospital in whose chests we were unable to satisfy ourselves that there was any amount of pus, and in the abdomen we have found up to 200 to 300 c.c. of fluid, a most distressing condition for anybody who tries to make a diagnosis.

We used the commercial serum at first, although we found later that the serum had little or no agglutinating power against Type I. We gave our patients standardized tincture of digitalis, and in the last series of thirty cases we used the autolyzed pneumococcic antigen prepared by Rosenow, and I believe that, while the epidemic has lost its virulence, the antigen has markedly affected not only our mortality but the incidence of the crisis in the true cases of pneumococcic infections.

DR. EDWARD F. WELLS, Chicago: The paper is of great and timely interest. The principle of protecting other persons from contact with infective organisms thrown into the air by pneumonia patients is clearly beyond question; the details may be adapted to meet the varied requirements, and have been mildly and incidentally mentioned at intervals during the past three or more decades. Recognizing the fact that the pneumococcus, once it obtains lodgment in the nose and throat, remains a permanent potential danger to its host, and that it may be conveyed to others by air which has been contaminated by coughing and sneezing, I have long, and frequently, advocated the placing of signs in public places to the effect that "In coughing or sneezing hold your handkerchief before your mouth and nose." I have no doubts as to the widespread beneficial prophylactic results which would follow the general adoption of this measure, and desire again to recommend its employment.

DR. EDWARD E. G. FRANING, Camp Dodge, Iowa: I was at Camp Dodge from the beginning and saw this whole epidemic. We were going along smoothly until all at once we were thrown into a sort of a convulsion by an epidemic striking us. There was nothing important about pneumonia before this epidemic came on. It seemed that we had said everything about pneumonia, but we found that there was a great deal to say. We are classifying pneumonias. We have divided them into two classes. One is the old-fasioned pneumococcus pneumonia and the other is the streptococcus pneumonia, which causes an interstitial type of disease. I am on the surgical side at Camp Dodge. We had some infections in our hernia work and in some cases of chronic appendicitis. We did everything we could to stop those infections, but we did not succeed. After a short time we were able to put the dirty work in one pavilion and the clean work in another place, and after that we had no more infections, showing that the infection was general throughout the hospital.

We had cultures made of the throats of the twenty surgeons on the service and found that about 18 per cent. had streptococci. The *Streptococcus hemolyticus* was present in probably 15 per cent., and there was one man who had the short-chained streptococcus—the nonhemolytic streptococcus. The point I want to make is that some of you will have those same germs in your own throats, and when an epidemic comes the percentage of these streptococci increases. The streptococcus was found in 60 or 70 per cent. of these sore throats. Any infectious disease will increase the streptococcus flora in the throat, so that it is no wonder that these streptococcus infections increase in the measles cases.

We could do necropsies. We found that those sore throats, the ulcerative throats, were accompanied by very red congested tracheas and bronchial tubes and interstitial pneumonias. A very simple streptococcus pneumonia resolves itself very easily, but at the top of the wave it is more severe, the infection is more virulent, more of the lung is involved.

The worst complication we had was empyema, and it was my misfortune to operate on nearly half the cases. Practically all those empyemas got well until the epidemic struck us, and then the death rate of the empyemas went up, in spite of any operative procedure. At the end of the wave, or when the wave was breaking, the death rate dropped right down, showing that any operation we did in those virulent cases was of no avail. It made no difference what operation you did, when the pneumonia was on the decrease the wave of death rate went down. So that we have to be very careful in deciding on the kind of treatment.

DR. GRANVILLE N. RYAN, Des Moines: It is our experience that you will get a favorable result in using glucose intravenously in the presence of an approaching coma or a dry tongue that is evidence of a dehydrated condition of the general system. It has been our experience that even a 10 per cent. solution of glucose has given very good results. We have added sodium bicarbonate in a 5 per cent. solution not only in pneumonia but in any dehydrated condition of the system or acidosis. I have not used glucose in 25 per cent. solution. In a delirious patient, instead of using opiates, try glucose, either alone or with sodium bicarbonate. You can make many of these patients more comfortable and, besides, these injections have a nutritive value.

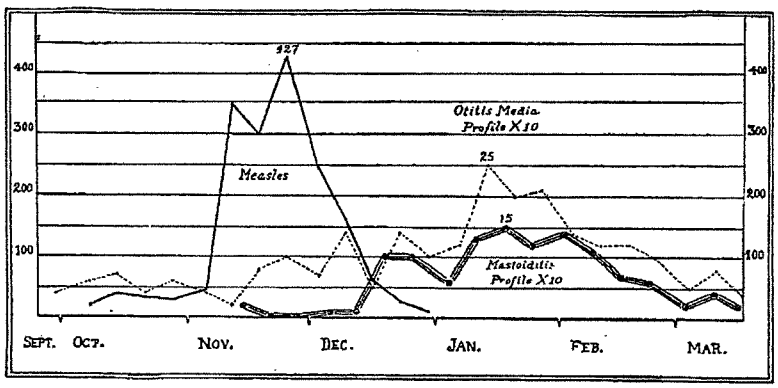
ACUTE MASTOIDITIS AS A COMPLICATION OF INFECTIOUS DISEASES

BASED ON A STUDY OF ONE HUNDRED AND TWENTY-THREE CASES IN THE BASE HOSPITAL, CAMP SHELBY, MISS.*

GEORGE H. LATHROPE, M.D.
Major, M. R. C., U. S. Army
MORRISTOWN, N. J.

During the past winter the southern Army camps seem to have been invaded by a widespread streptococcus infection, expressing itself somewhat differently here and there; but in its most virulent form, and with highest mortality, in the shape of an involvement of the lung or pleura or both, by the *Streptococcus hemolyticus*.

Camp Shelby was no exception to the general rule, but for unexplained reasons, which the epidemiologist must elaborate for us, the infection was not of the severest type, as there occurred only about 300 cases of pneumonia and thirty-five cases of empyema. However, in studying the streptococcus cases as a whole, a striking variation from the general rule is at once apparent, in that, among the empyemas, the hemolytic streptococcus is not the prevailing agent of infection. While there are a few due to this type of streptococcus, by far the larger number, as shown in the study by Captains Todd, Moore and Zingher, are due to a streptococcus of the *S. viridans* group. There have been a considerable number of patients having streptococcus infections of organs other than the lung and pleura, and when one glances over this division another exception is evident, in that there is a large number who suffered invasion of the middle ear and mastoid. It is this group that constituted our peculiar problem. By itself, this cannot be considered as an entity but as a curious phase of the broad streptococcus problem; and as one phase only of that larger question do I propose to deal with it.



Curve designed to show measles, otitis media and mastoid admissions to the hospital by weeks. The otitis media purulenta and mastoid scales bear a ratio to the measles scale of 10: 1; i. e., to read, substitute the numbers 10, 20, etc., for 100, 200, etc. The numbers at the acme of each curve indicate the largest total admissions for one week.

In all, 123 soldiers developed acute mastoiditis of one or both sides. Invariably there was a preceding middle ear involvement; though in several cases the invasion of middle ear and mastoid had the appearance of being synchronous, so rapidly did the infection mature.

It was a common occurrence that a patient complained in the night of earache, and the next morning was found to have a reddened, bulging drum, which would be opened at once. Mastoid tenderness was an accompaniment of the middle ear symptoms, and the second morning, the tenderness persisting, and the temperature remaining high, even with free drainage, the roentgenogram would reveal a cloudy mastoid, leukocytes would be high, and at operation within forty-eight or seventy-two hours of the onset of the first symptoms, an extensive involvement of the mastoid with necrosis and thick pus would be found. Others of our cases were slower in onset; there were some in which we felt that we had not attacked the middle ear early or vigorously enough; but so many developed rapidly right under our eyes, despite the promptest care in the shape of paracentesis and roentgen examination of the mastoids, that we could not escape the conclusion that we were dealing with a highly virulent organism which had a definite predilection for these tissues.

Turning now to the relation of this "epidemic" of mastoiditis to preexisting diseases in the camp, our attention is first attracted to the outbreak of measles. The graphic chart shows that the mastoid cases occurred mainly in the period from December 15 to February 1. The curve of the measles epidemic begins in October, reaches its height in late November, and declines abruptly in January. The curve of the otitis media and mastoid cases follows this rather graphically. The otitis media curve here shown represents 240-odd cases. This number must not be misunderstood to represent the total number of otitis media purulenta cases in camp. It gives merely those cases treated in the wards of the base hospital and does not include either the cases treated by the ear clinic or at the regimental infirmaries, which never entered the hospital, and of which we have there no record. Consequently it does not represent, nor is it intended to represent, anywhere near the total number of otitis media cases from which the mastoid series developed. It is merely put in as exhibiting in a general, but fairly accurate way, the determination of the curve of the entire group of middle ear infections. It must be remembered that December and January were the months of the greatest incidence of all the acute respiratory affections, and these too, as we shall see, played a most important part in the development of mastoiditis.

Table 1 shows the relation of the mastoid cases to the various diseases that preceded them immediately

* Read before the Section on Practice of Medicine at the Sixty-Ninth Annual Session of the American Medical Association, Chicago, June, 1918.

Exhibit #7

The U.S. Military and the Influenza Pandemic of 1918–1919

CAROL R. BYERLY, PHD[a]

SYNOPSIS

The American military experience in World War I and the influenza pandemic were closely intertwined. The war fostered influenza in the crowded conditions of military camps in the United States and in the trenches of the Western Front in Europe. The virus traveled with military personnel from camp to camp and across the Atlantic, and at the height of the American military involvement in the war, September through November 1918, influenza and pneumonia sickened 20% to 40% of U.S. Army and Navy personnel. These high morbidity rates interfered with induction and training schedules in the United States and rendered hundreds of thousands of military personnel non-effective. During the American Expeditionary Forces' campaign at Meuse-Argonne, the epidemic diverted urgently needed resources from combat support to transporting and caring for the sick and the dead. Influenza and pneumonia killed more American soldiers and sailors during the war than did enemy weapons.

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In the fall of 1918, U.S. Army and Navy medical officers in camps across the country presided over the worst epidemic in American history, but the story was not new. War and disease have been linked throughout history as armies, weapons, and human pathogens have met on the battlefield. The conquistadores brought with them diseases that devastated the New World; typhus plagued Napoleon's armies; and typhoid fever humiliated the American Army during the Spanish-American War. But now U.S. Army and Navy personnel knew how to test and sanitize water supplies, vaccinate troops against typhoid and smallpox, and treat or prevent other infections. Modern bacteriology, it seemed, had tamed many diseases. Navy Surgeon General William C. Braisted proudly stated that "infectious diseases that formerly carried off their thousands, such as yellow fever, typhus, cholera, and typhoid, have all yielded to our modern knowledge of their causes and our consequent logical measures taken for their prevention."[1]

Twentieth-century warfare, however, had evolved to an even more deadly scale as industrialized armies of millions battled on the plains of Eastern Europe, the cliffs of Gallipoli, and in the deadly trenches of the 550-mile-long Western Front. When the European arms race exploded into war in 1914, the empires shocked themselves and the world with the killing power of their artillery and machine guns, their U-boats and mines, and their poison gas. These new weapons generated new, horrible injuries that took life and limb in a flash or festered into gangrenous wounds that could further maim and kill. The carnage traumatized some men into shellshock, and poison gases burned and suffocated others so horribly that nurses dreaded caring for them because they could provide little comfort. War diseases—notably the soldiers' nemeses diarrhea, dysentery, and typhus—flourished, and the trenches offered new maladies such as "trench foot," an infection caused by wearing sodden boots and standing in water and mud for days on end, and "trench fever," a debilitating fever transmitted by body lice.

Then, in the fourth dreadful year of the war, as the American Expeditionary Forces (AEF) assumed fighting strength and prepared their first great offensive against the Germans, the flu struck. By the War Department's most conservative count, influenza sickened 26% of the Army—more than one million men—and killed almost 30,000 before they even got to France.[2,3] On both sides of the Atlantic, the Army lost a staggering 8,743,102 days to influenza among enlisted men in 1918.[4] (p. 1448) The Navy recorded 5,027 deaths and more than 106,000 hospital admissions for influenza and pneumonia out of 600,000 men, but given the large number of mild cases that were never recorded, Braisted put the sickness rate closer to 40%.[5,6] (p. 2458)

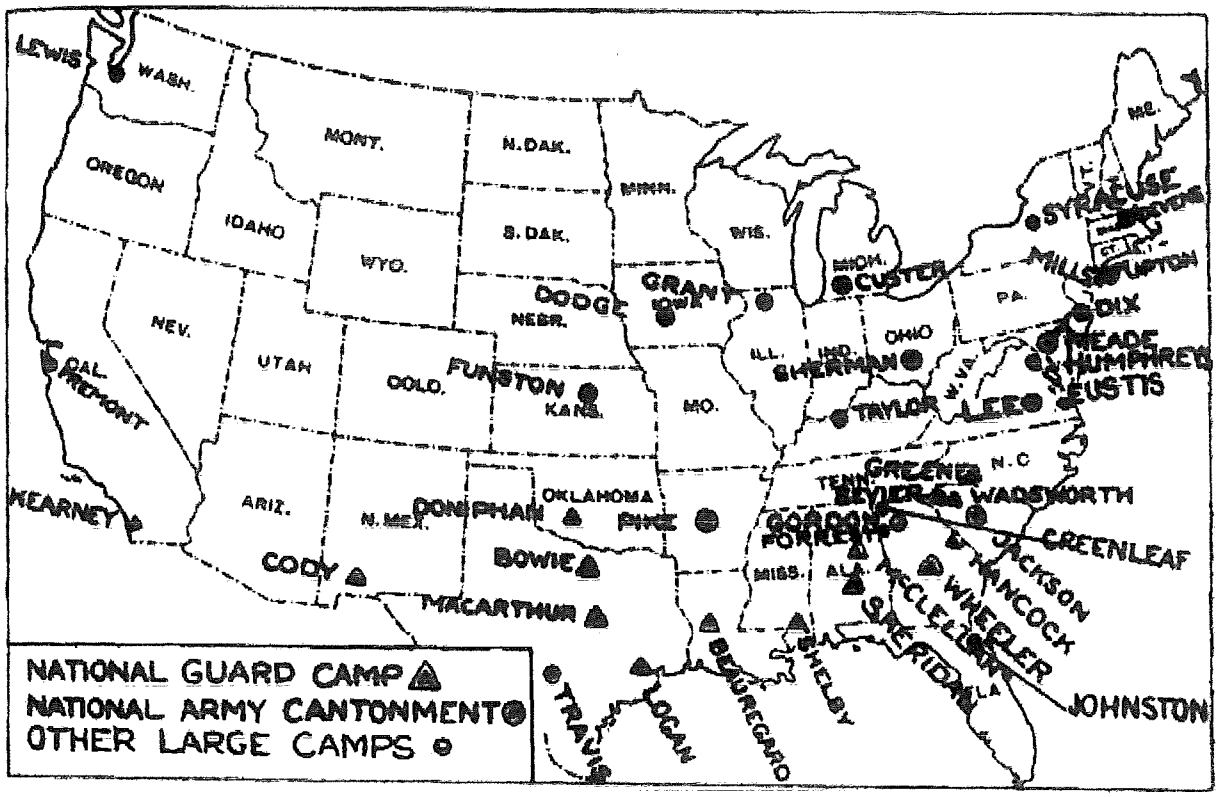
The Army and Navy medical services may have tamed typhoid and typhus, but more American soldiers, sailors, and Marines would succumb to influenza and pneumonia than would die on the industrialized battlefields of the Great War. The story of the influenza epidemic in the military is often lost in the historical narrative of the Great War, included merely as a coda to that four-year horror, coinciding with the final battles and the Armistice. But an examination of medical reports and War Department and Department of the Navy documents from the war reveals that the war and the epidemic were intertwined.[7] World War I and influenza collaborated: the war fostered disease by creating conditions in the trenches of France that some epidemiologists believe enabled the influenza virus to evolve into a killer of global proportions. In turn, disease shaped the war effort by rendering much of the Army and Navy non-effective and diverting resources, personnel, and scarce human attention and energy from the military campaign. The exigencies of war also thwarted many of the efforts such as crowd mitigation and quarantines to control the epidemic. The influenza epidemic in the U.S. military therefore provides a cautionary tale about the power of war to change the health environment and the power of disease to influence the conduct of war.

GOING TO WAR

The United States at first hung back from the killing in Europe, as many Americans believed it was not their fight. But under increasing pressure from Britain and France, and angered by German U-boat attacks that threatened American commerce and security, and the revelations in the Zimmermann Telegram that Germany was urging Mexico to attack the United States, President Wilson abandoned neutrality and in April 1917 asked Congress for a declaration of war.

The U.S. economy was already booming as farmers and manufacturers shipped foodstuffs and military supplies to the belligerent nations. Now the United States would also generate its own military force that would help overwhelm the enemy and bring about the armistice of November 11, 1918. Congress quickly established a draft, and more than 4,600 Selective Service draft boards screened 10 million men to find the strongest and most fit soldiers and sailors. The military grew from just 378,000 strong in April 1917 to more than 4.7 million by war's end, with an Army of 4.1 million and a Navy of 600,000. Seventy-two percent of enlisted forces were inducted, and the military

Figure 1. Locations of Army training camps in the U.S. in 1918



Source: War Department (US). Annual report, 1919. Washington: Government Printing Office; 1920. p. 1519.

population reflected the country's ethnically diverse and racially segregated society. An estimated 20% of Army draftees were foreign-born and the troops spoke at least 46 languages, some 5,700 were Mexican aliens, and 12,500 were American Indians.[8] (p. 367-409) More than 400,000 African Americans served in the Army, some in two black combat divisions but most in labor battalions. The Navy employed only 5,300 black sailors, confining them to positions as cooks and stewards.[9]

War mobilization drew millions of civilians into military institutions and extended the military into all corners of the country. To train and supply these men, the Army and Navy expanded existing facilities and directed training activities at various civilian organizations. Military camps, arsenals, air fields, and supply depots sprouted up in every state. The Army began training recruits in the fall of 1917 at 32 large camps, each home to 25,000 to 55,000 troops. Soldiers also went to specialized camps for training in specific fields such as artillery training at Camp Knox, Kentucky, railway operations at Camp Benjamin Harrison in Indianapolis, military engineering at Camp Forrest, Georgia, and medical unit training at Camp Crane, Pennsylvania. The War Department also operated some 40 air fields for aviator training and 10 embarkation and debarkation camps.[8] (p. 677–78) The Navy expanded its training capacity from 6,000 recruits to more than 100,000 at stations on both coasts, the Gulf of Mexico, and Lake Michigan, and also had specialized training centers such as the Navy gas engine school and the aviation ignition school at Columbia University in New York. In addition to the training camps, in the summer of 1918 the War Department established the Student Army Training Corps (SATC), intended to augment the work of the Reserve Officers Training Corp (ROTC) and prevent war mobilization from emptying institutions of higher education. Under the program, more than 500 colleges and universities trained officer candidates and provided technical instruction in fields such as auto mechanics and radio operation. By the Armistice, about 158,000 young men had enrolled in SATC programs.[8] (p. 556) This expansion of military institutions created a virtual network of young adults across which influenza could and would travel (Figure 1).

As the Army grew, the Army Medical Department raced to meet its needs. Military medicine was more like public health medicine (which managed large

populations) than private medicine (which focused on care for individuals). By necessity, line officers cared less about who was sick or on leave than who they could send into battle. This was called the "effective" rate—how many men were available in a given unit to work and fight. Medical officers therefore tried to keep non-effective rates as low as possible, and measured their success statistically more than by individual patient care. The Army Medical Department tracked sickness in camps, combat units, labor battalions, ports, and ships by the day, week, month, and year, and compared its record with civilians, earlier wars, and other armies. Army Medicine also combined the old sanitation model of clean water and fresh air with the new public health approaches of educating soldiers on how to stay healthy and prevent disease. Army Surgeon General William C. Gorgas came out of the sanitary tradition and stressed good food, clean water, fresh air, and no crowding, but like other Progressives, also saw the Army as an opportunity to instill young men with middle-class values such as good personal hygiene.[10]

To care for the growing Army, the Medical Department increased its hospital capacity from 9,500 beds to 120,000 in the United States alone. The Red Cross assisted by recruiting trained nurses for the Army Nurse Corps and organizing ambulance companies and 50 hospitals of 1,000 beds each out of American universities and medical institutions. The Army Medical Department ultimately numbered 30,500 medical officers, 21,500 nurses—including 350 African American physicians but no black nurses until December 1918—and 264,000 enlisted men.[8] (p. 257) The Navy Bureau of Medicine and Surgery had some 3,000 medical officers, 1,700 nurses, and 11,000 enlisted men.[5] (p. 2066, 2073) As one civilian public health official pointed out, with almost 30% of American physicians in military service, ". . . there were sections of the country that were absolutely stripped of physicians." During the pandemic in civil society, therefore, ". . . the great majority of available, medical and nursing personnel, were already in the Army or Navy, so that the available personnel from which to draw was limited."[11]

World War I was largely a ground war, so the Army bore the brunt of the fighting. While some 55,000 Marines served with the AEF, most of the Navy's responsibilities involved patrolling for U-boats, sweeping for enemy mines, escorting troop and cargo ships across the Atlantic, and mining the North Sea against the German Navy. Mobilization got off to a slow start in the United States, and a year after the declaration of war, the AEF in Europe numbered fewer than 400,000. By May 1918, however, hundreds of thousands of soldiers were crossing the Atlantic each month to build a combat force of two million by November. This transport of an army to another continent and back was one of the great achievements of World War I and demonstrated the power of the American government and economy. But such triumph also carried danger because as the doughboys traveled "Over There," they did not travel alone.

A LETHAL VIRUS

Influenza sailed with American troops across the Atlantic and when it exploded in late August and September in Europe and the United States, medical officers found themselves on the front lines of an epidemic worse than any of them had ever seen or imagined. Many were among the most knowledgeable and skilled physicians in the country and had just recently entered military service. They did their best to save those stricken by influenza, but could do little more than provide palliative care of warmth, rest, and a gentle diet, and hope that their patients did not develop pneumonia.

One of the tragedies of the influenza epidemic is that by the 1910s, the medical profession held many of the scientific and epidemiological tools to understand the nature and extent of the damage influenza and pneumonia were wreaking on their patients, but lacked the tools to effectively fight them. While virology would not emerge until the 1930s, physicians could identify many of the bacteria causing the deadly pneumonias that were killing their patients, but without antibiotics they could do little to fight the infections. Thus, as the epidemic struck their camps, hospitals, ships, ports, or divisions, many medical officers documented what they saw, as if trying to define that which they could not control. They ran tests and did autopsies, recorded their laboratory and clinical findings, compared morbidity and mortality rates across time and with other units, and tried to stay healthy themselves. They wrote detailed reports to their superiors and published myriad articles on the influenza of 1918–1919. These studies and reports would provide some of the most extensive documentation on the pandemic, informing civilian and military researchers alike as they struggled for years after the war to understand what had caused the epidemic and its widespread suffering.[2,4,5,7]

As they conducted their analyses, military medical officers soon understood that the wave of influenza that had run through many U.S. training camps during the spring of 1918 constituted a first wave of the pandemic. Fourteen of the largest training camps had reported influenza outbreaks in March, April, or May, and some of the infected troops carried the virus with them aboard ships to France.[12] In the late

spring and summer, influenza visited all of the armies of Europe, including the AEF, but because influenza was common in the military, and few patients became critically ill, medical officers were not alarmed. But by the late summer some saw the emergence of a new, lethal influenza.

Captain Alan M. Chesney, medical officer with an AEF hospital at Valdahon, an artillery training camp behind the front lines in France, documented the evolution of a more virulent influenza from his vantage point. A physician who was later dean of the Johns Hopkins Medical School, Chesney noted that three different infantry brigades of 4,000 men occupied the post in succession, "thus every three or four weeks there occurred a marked change in the population of the post." He theorized that "the history of the epidemic, therefore, resolved itself into distinct periods corresponding to the various brigades which entered the post," and "the frequent changes in the population of the post, brought about by the short stay of each brigade, exercised considerable influence upon the course of the epidemic of influenza."

During Chesney's first documented period, the month of June to July 27, the 5th Artillery Brigade had 77 "relatively mild" cases of influenza. During the second phase, July 27 to August 23, 200 men of the 58th Artillery Brigade became ill, about 6.5%. None of them died, but the outbreak was serious enough that the next brigade cleaned out the barracks, even washing the walls, before they moved in. Despite this precaution, during Chesney's third phase, August 23 to November 8, more than one-third of the 6th Artillery Brigade, 1,636 soldiers, contracted influenza and 151 died. Chesney concluded that ". . . these successive outbreaks tended to be progressively more severe both in character and extent, which would speak for an increasing virulence of the causative agent."[13]

Medical officers such as Chesney wanted clean barracks and also worried about crowding. Surgeon General Gorgas had recommended that Army housing provide 60 square feet per man, but did not often prevail. As Gorgas told one training camp commander, "We know perfectly well that we can control pneumonia absolutely if we could avoid crowding the men, but it is not practicable in military life to avoid this crowding."[14] The Medical Department even asserted that "there is to be expected a definite relation between the degree of crowding and the amount of respiratory infection."[2] (p. 111) But if it was difficult to control crowding in the training camps, it was impossible in the battlefields. Evolutionary biologist Paul Ewald has argued that trench warfare and its crowded conditions enabled an especially aggressive and deadly influenza virus to gain footing in humans.[15] As soldiers in the trenches became sick, the military evacuated them from the front lines and replaced them with healthy men. This process continuously brought the virus into contact with new hosts—young, healthy soldiers in which it could adapt, reproduce, and become extremely virulent without danger of burning out. From there, according to a Navy report, "It is reasonable to suppose that late in August influenza of severe type was spread from French, Spanish, and Portuguese seaports to the Orient, South Africa, the United States, and South America."[5] (p. 2427) As Chesney and Ewald suggest, the influenza of 1918 was a product of trench warfare, and the influenza that attacked the 6th Artillery at Valdahon would travel the highways of war, circling the globe.

INFLUENZA IN THE CAMPS

Braisted pinpointed the arrival of the epidemic in the United States to Tuesday, August 27, 1918, at Commonwealth Pier in Boston ". . . when three cases of influenza were committed to the sick list." The next day produced eight cases, and on August 29, 58 cases were reported, 15 so ill they were transferred to the U.S. Naval Hospital in Chelsea.[5] (p. 2427) Within 48 hours, three medical officers who had seen the patients also fell ill.[5] (p. 2473–4) Influenza reached civilians in Boston and on September 8, arrived "completely unheralded" at the Army's Camp Devens, outside of the city. Within 10 days, the base hospital and regimental infirmaries were overwhelmed with thousands of sick trainees.[16,17]

Gorgas sent his best epidemiologists to Camp Devens to investigate. His team included Victor C. Vaughan, dean of the University of Michigan School of Medicine and director of the Surgeon General's Office of Communicable Disease; William Henry Welch, famed pathologist from Johns Hopkins; and Rufus Cole, respiratory diseases expert from the Rockefeller Institute.[18] They found the medical situation "grave," and recommended 16 measures to control the outbreak, the most dramatic being a halt to transfers in or out of Devens until the epidemic passed. Camp Devens physicians performing autopsies described influenza pathology as unique, characterized by "the intense congestion and hemorrhage" of the lungs.[19] Cole and Welch observed one such autopsy, and Cole noted that Welch, "turned away from the blue, swollen lungs with wet, foamy, shapeless surfaces [and] became excited and nervous, saying, 'This must be some new kind of infection or plague.'" Added Cole, "It was not surprising that the rest of us were disturbed, but it shocked me to find that the situation, momentarily at least, was too much even for Dr. Welch."[20]

But as Vaughan and Welch investigated Camp Devens, the virus kept moving. Before any travel ban could be imposed, a contingent of replacement troops departed Devens for Camp Upton, Long Island, the Army's debarkation point for France, and took influenza with them. Medical officers at Upton said it arrived "abruptly" on September 13, 1918, with 38 hospital admissions, followed by 86 the next day, and 193 the next. Hospital admissions peaked on October 4 with 483, and within 40 days, Camp Upton sent 6,131 men to the hospital for influenza. Some developed pneumonia so quickly that physicians diagnosed it simply by observing the patient rather than listening to the lungs. "The patient looked sick and suggested a serious condition," they wrote, "his face was often cyanotic, sometimes ashy, sometimes just pinched looking. He expressed no pain or suffering. If his mind was clear he expressed a sense of euphoria, or of unnatural realization of his condition, which in particular marked the advanced stages of the disease."[21] Private James Downs entered the hospital on September 23 with a temperature of 104 degrees and died three days later. An Army pathologist clipped a piece of Downs' lungs and sent it to the Army Medical Museum as a specimen of the damage influenza was doing to young soldiers.[22] As they walked through Camp Upton's pneumonia wards of 900 patients, medical officers experienced "horror at the frightfulness of the sight of the hopelessly sick and dying and at the magnitude of the catastrophe that had stricken wholesale the young soldiers prepared to face another enemy but helpless before this insidious one." That sight, they said, "will haunt for life the minds of those who saw it."[21]

In efforts to contain the outbreak, Camp Upton's commander John Mallory put its 30,000 inhabitants under quarantine, barring travel in and out except on "the most urgent business."[23] But in wars and epidemics there is much urgent business and people got through. Naomi Barnett of Brockton, Massachusetts, had sped to Upton to care for her fiancé Jacob Julian when she learned he was ill. They planned to be married before he departed for duty in France but the young woman died of pneumonia two days after arriving at the camp. Her beloved died 30 minutes later. "Relatives," reported the local newspaper, "are planning a double funeral in Brockton."[24] To control influenza and pneumonia, the hospital provided patients with 100 square feet of floor space, separated beds by sheets, and furnished face masks to everyone in the camp. As pneumonia spread, medical officers also sprayed the mouths and throats of 800 healthy men daily with the solution of dichloramine-T as a preventive measure, but when they compared their influenza rates with 800 untreated men, they were disappointed to find that "...over a period of twenty days the incidence in the two groups was the same."[2] (p. 121)

As Upton medical officers climbed the peak of their epidemic, the virus traveled west and south, arriving at Camp Grant, Illinois, on Saturday, September 21, 1918, with 70 hospital admissions. "So sudden and appalling was the visitation that it required the greatest energy and cooperation of every officer, every man, and every nurse to meet the emergency," wrote one observer.[4] (p. 749) Hospital admissions rose to 194, then 370, then 492, to a high of 788 admissions on September 29. Hospital officials summoned all officers on leave, converted barracks to hospital wards, and by "extreme effort" expanded the hospital capacity from "10 occupied beds to a capacity of 4,102 beds in six days."[4] (p. 751) Influenza still overwhelmed every department. The hospital laboratory resorted to local civilian facilities to perform specimen tests. Camp ophthalmologists saw patients with conjunctivitis, an influenza complication, and ear, nose, and throat specialists saw those with other dangerous secondary infections. As individuals became seriously ill, camp officials sent out "danger" or "death" telegrams to families and loved ones, but soon they received so many return calls, telegrams, and visitors, they had to set up a separate hospital tent as an information bureau. Medical personnel were not immune. Eleven of the 81 medical officers fell ill, and three civilian and three Army nurses died. The epidemic even caused the Medical Department to drop its prohibition on black nurses so that Camp Grant called African American nurses to care for patients. The women had to wait, however, until separate, segregated accommodations could be constructed.[25]

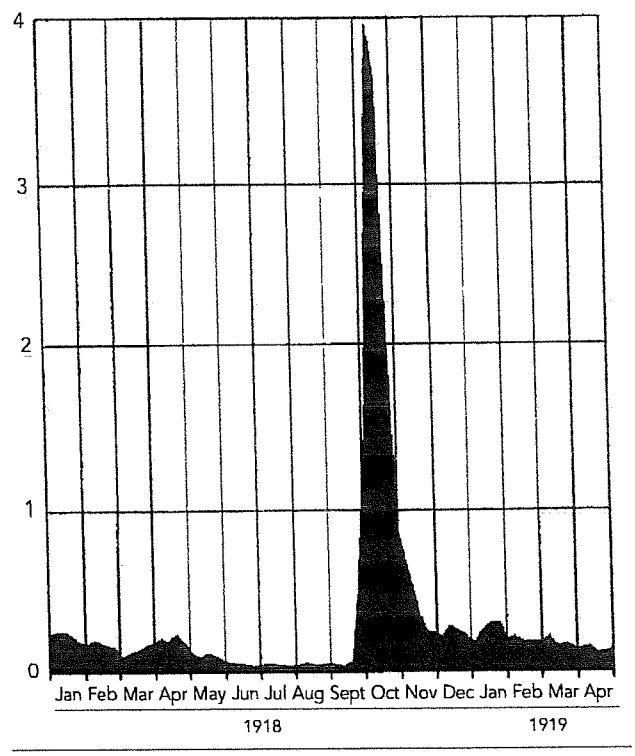
Ten days after the epidemic struck, hospital admissions began to fall but pneumonia took hold, and Camp Grant's daily death toll began to climb. It reached double digits on October 1 with 14 deaths, then 30 the next day, 46 the next, and 76 on October 4. The mortuary was designed to handle only four deaths a day. On Friday, October 4, with more than 100 bodies in the mortuary camp, officials negotiated with local undertakers to take the bodies at $50 each, but when someone produced a flatbed truck to remove the dead, the Army quickly provided more dignified closed trucks. The number of dead broke 100 on October 5 and reached a horrifying high of 117 deaths on October 6.[4] (p. 750–4) The last day the Camp Grant death toll exceeded 100 was October 9, but the decline was too late for its commander. Col. Charles B. Hagadorn, a West Point graduate and career officer who had served in Russia and the Panama Canal Zone, was acting camp commander when influenza struck. Although

Camp Grant's sickness and death rates were no worse than other camps and better than some, fellow officers later told reporters that Hagadorn had been showing the strain of the epidemic.[26,27] Troubled as more than 500 soldiers died of pneumonia under his command, on October 7, he committed suicide with a pistol shot to his head. In the end, Camp Grant suffered 10,713 influenza victims, including 1,060 deaths in a population of 40,000.[4] (p. 749)

Across the country, medical officers noted the rapidity with which the epidemic hit each camp, in some cases reaching its highest number of cases within 10 days (Figure 2).[5] (p. 2429) The steep gradient of the flu attacks can be seen in the headlines of *The Camp Dodger*, the weekly newspaper of Camp Dodge, Iowa, which strobe the trajectory of the epidemic. The flu struck on September 29, so its first mention is an October 4 headline: "Dodge Battles Spanish 'Flu'; Impose Quarantine, Cases Number 1500, One Death Reported." The next week's front page announced, "Flu Epidemic Subsiding; Fewer New Cases; Death Rate Is Low," and the following week's headline read, "Peak Flu Scourge Has Passed." Influenza disappeared from the front page of the October 25 edition, and the November 1 front page noted, "Services in Memory of Dodge Dead; Soldiers and Civilians Will Pay Tribute Sunday to Victims of Epidemic."[28–31] And that was it. Although Camp Dodge would have one of the worst records among Army camps with more than 13,700 hospital admissions and 700 deaths, the epidemic had passed and the Armistice dominated the news.[4] (p. 2017)

Influenza reached all Army training camps in a month, arriving September 8 at Camp Devens, September 13 at Camp Upton, September 21 at Camp Grant, September 26 at Camp Cody, and then on to the West Coast, arriving October 8 at Camp Fremont, California, and October 9 at Camp Lewis, Washington.[2] (p. 138) War Department training reports show that as influenza arrived at each camp, it "interfered with," "curtailed," "brought to a standstill," or even caused the discontinuation of training activities as recruits and instructors fell ill.[32] The deadly second wave of the epidemic lasted about four weeks in individual camps and ran its course in the Army in about eight weeks, roughly from September 15 to November 15, 1918. The high-water mark for deaths in the United States came the week of October 4 and in the AEF, the week of October 11.[4] (p. 2755) Navy and Army officers observed that the U.S. camps had higher morbidity and mortality rates than shipboard sailors or AEF soldiers and Marines; one report set hospital admissions for influenza at 167 per 1,000 in the AEF compared to 361 per 1,000 in the U.S.

Figure 2. Deaths per 1,000 soldiers each week during 1918–1919 in the U.S. Army

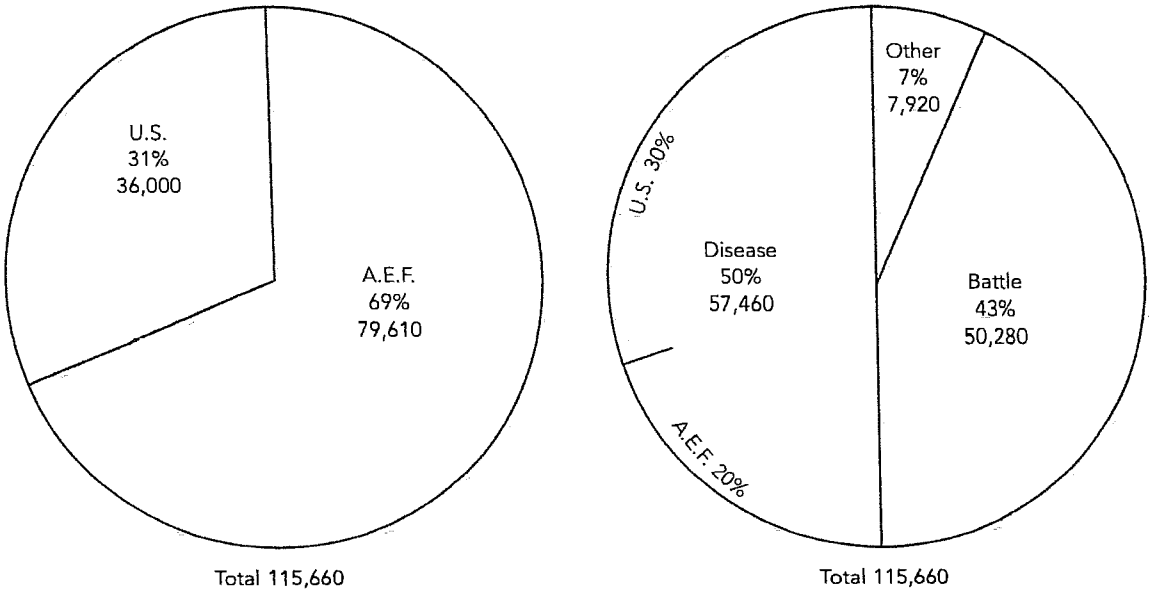


Source: Ayres LP. The war with Germany: a statistical summary. Washington: Government Printing Office; 1919. p. 127.

camps.[4] (p. 1469) Officers believed this was because deployed personnel had been exposed to influenza in an earlier wave and therefore had some immunity to the second deadly wave.[5] (p. 2414)

In some camps, African American soldiers had lower morbidity but higher mortality rates than white soldiers, and some medical officers erroneously attributed this to racial weakness and susceptibility. But segregation, ironically, may have shielded some black units from influenza infection, and the higher mortality could have been due to African Americans' often inferior living conditions and medical care in the military. Segregation in the Army was rarely "separate but equal." One study of the army rations allocated to men at camps Grant, Dodge, and Funston over four months revealed that the 366th Infantry of the Ninety-second Division, one of the black combat divisions, received less protein and fewer calories than the white units, even though they were on the average taller and heavier than their white counterparts.[33] Private Robert Stevens of Louisiana, with the 803rd Pioneers, a black unit that fought in the Meuse-Argonne, also remembered that when several hundred men in his regiment were sick with pneumonia, they had only one medical officer.[34]

Figure 3. Total deaths in the U.S. Army including Marines attached to it: April 6, 1917, to July 1, 1919



Source: Ayres LP. The war with Germany: a statistical summary. Washington: Government Printing Office; 1919. p. 123.
A.E.F. = American Expeditionary Forces

In Europe, influenza attacked Allied and German armies alike, filling field hospitals and transport trains with weak, feverish men all along the Western Front. On October 18, the AEF chief surgeon reported that ". . . influenza and pneumonia continue to prevail in all parts of the A.E.F."[35] Influenza cases outnumbered combat casualties. According to one tally, 227,000 soldiers were hospitalized for battle wounds in 1918, but half again as many AEF soldiers—340,000—were hospitalized for influenza.[4] (p. 1429–41) The epidemic struck during the climax of the American military effort, compromising the AEF's performance in its largest campaign of the war, the Meuse-Argonne Offensive. Influenza clogged transportation lines along the battlefront, choked hospitals, killed thousands of soldiers, and rendered many more non-effective. The flu depleted and demoralized troops, and may have diverted military and political leaders from fighting the war to combating disease. It ultimately killed more American military personnel than did enemy machine guns and artillery (Figure 3).

THE ARMY AND NAVY RESPOND

As he watched the epidemic unfold, Acting Army Surgeon General Charles Richard warned the Medical Corps that ". . . no disease which the army surgeon is likely to see in this war will tax more severely his judgment and initiative."[36] His office distributed numerous bulletins on influenza and pneumonia to Army personnel and fired off daily memos to Army Chief of Staff Peyton March and others making recommendations on the epidemic.[37,18] Concerned about influenza spreading on crowded troopships, Richard advised March against sending troops from infected camps to France until the epidemic was over in their region.[18] March approved this recommendation, which at first affected only a few training camps. But as the epidemic widened, Richard called for canceling all draft calls for registrants destined for infected camps and minimizing transfers between camps. "Epidemic influenza has become a very serious menace," he told March, "and threatens not only to retard the military program, but to exact a heavy toll in human life, before the disease has run its course throughout the country."[18,38] March's office instructed camp commanders to reduce crowding and increase medical personnel, but halted only some of the draft calls, so that in late September new recruits were still entering training camps. Only the Provost Marshall's cancellation of the October draft finally eased pressure on the camps.[39]

Richard also recommended a one-week quarantine of all troops prior to embarkation and reducing the capacity of troopships by one-half. Desperate to build up the forces in France, March rejected these suggestions in favor of rigorous pre-boarding physical screening to control the epidemic. Richard countered: "It is impossible for medical officers to state with any degree of safety that any particular command is free from infection, or that it may safely embark on troopships

for overseas service." He then recommended "that all troop movements overseas be suspended for the present, except such as are demanded by urgent military necessity."[18] Richard was willing to suspend war mobilization to protect the health of the soldiers. March agreed to a 10% reduction in crowding on troopships, but that was all. The controversy reached the White House when President Wilson asked March why he refused to stop troop transport during the epidemic. March described the Army's screening precautions and invoked the exigencies of a war of attrition, pointing out ". . . the psychological effect it would have on a weakening enemy to learn that the American divisions and replacements were no longer arriving."[40] Troop shipments should not be halted for any reason, he told Wilson, and the president deferred to his judgment. March and Wilson had no intention of retarding U.S. participation in the war. By mid-October, however, the practice of taking men from camps that had already weathered the epidemic did finally reduce the influenza rates on troopships and in the AEF.

Sickness rates in U.S. camps ultimately ranged from 10% at Camp Lewis, Washington, to 63% at Camp Beauregard, Louisiana, averaging between 25% and 40%; death rates ranged from less than 1% at many camps to 3.3% at Camp Sherman, Ohio.[2] (p. 138) But the sickness rates probably understated the problem because they captured only those soldiers who reported sick and received medical attention. Army investigators found that some regimental physicians did not send soldiers to hospitals unless they had temperatures higher than 101 degrees.[4] (p. 3794) Many stricken soldiers may have just stayed in bed with or without knowledge or permission of their superior officers. Others may have gone home when they got sick, either with leave or AWOL. "One of the boys played wise and got sick while he was home," Charles Johnston, a soldier at Camp Funston, Kansas, wrote home in early October. "He is down with pneumonia, so will have a prolonged visit while home. Think I will try that when I come home, eh!" Several days later Johnston reported, "There have been hundreds of boys taken A.W.O.L. since [the camp was] quarantined."[41] The situation became so bad that the War Department ordered the investigation of absentees from government service.[42]

While the implementation of treatment and prevention measures varied from camp to camp, medical officers generally tried "all preventive measures which seemed logical," according to Braisted. Quarantines were almost impossible to maintain and had little effect. The Navy, rushing to transport troops across the Atlantic, imposed modified quarantines at many stations but ". . . invariably this measure failed to prevent the introduction of influenza."[5] (p. 2486) As the Army Medical Department explained, ". . . to be of avail in excluding influenza, quarantine must more nearly approach perfection than proved practicable in the large camps of the war."[2] (p. 116) Other prevention measures included daily inspections and temperature-taking, patient isolation, face masks and gowns for attendants, good ventilation, screening between beds, prohibition of indoor gatherings, nose and throat sprays for the healthy, and experimental vaccines. In assessing these measures, however, Braisted concluded that "each particular preventive measure failed in some instances to accomplish recognizable results."[5] (p. 2483) The Army Medical Department similarly admitted that "the best result to be expected from any or all of these measures is a slowing of the progress of an epidemic rather than any considerable diminution in the number of cases."[2] (p. 123-4)

The Great Lakes Naval Training Station in Rockford, Illinois, provided an example of a failed measure. When it offered masks to personnel, only 96 out of 674 hospital corpsmen wore them and they experienced a higher influenza rate than those who did not wear masks—8.3% compared with 7.9%.[5] (p. 2490) Great Lakes was by far the largest Navy camp, with a population of 44,000, and influenza arrived with "explosive violence" on September 16 and within 30 days generated 9,623 cases.[5,11] (p. 2430) Harney Stover, a sailor from Indiana training at Great Lakes, explained to his mother that influenza "affects most men pretty hard for the first few hours. They turned ashen gray and usually faint." He commented that "at the rate it is spreading, everyone will have had it and be well in a week," but he was overly optimistic.[43] Within weeks hundreds of his fellow trainees would die, as would many of those who were caring for them.[5] (p. 2452) Although only one Navy nurse had died during the war to date, 25 succumbed to the pandemic, seven of them at Great Lakes camp: Theresa Burmeister, Myrtle Grant, Edith Hokanson, Emma Kotte, Alice Lea, Garnet Olive Peck, and Amber Story.[5] (p. 2071)

Stover escaped the flu but chafed at the quarantine. He was furious when a local mayor objected to lifting it. "When we get liberty once more the mayor of Waukegan is going to have his darn little town run off the map and get tar and fethered [sic] himself." But if it was difficult to contain the influenza virus, it was harder to contain sailors and soldiers. When false rumors of an armistice hit the camp, "the whole station went wild," wrote Stover. "In the next Regiment, they tore the doors off 2 barracks trying to get out. . . . It was almost an hour before the Provost Guards could make everybody get back in their barracks."[43]

When the Armistice finally came on November 11, it was impossible to maintain quarantines, but by then influenza had passed through most camps, leaving much to celebrate and to mourn. Influenza would again sweep American military camps in the United States and Europe in early 1919, but would be less virulent than the previous wave and find less fuel, as demobilization rapidly depopulated the camps. While the U.S. military had helped to subdue the Germans, the medical profession had failed to conquer an even more deadly, unseen enemy. Now in peacetime, thousands of physicians left military service to return to civilian life, taking with them their searing experiences of war and disease, victory and defeat.

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Exhibit #8

WAR DEPARTMENT

Annual Reports, 1919

(IN THREE VOLUMES)

Volume I

(IN FOUR PARTS)

▽

Part 4

Reports of

THE CHIEF OF ORDNANCE
THE CHIEF OF MILITIA BUREAU
THE CHIEF OF COAST ARTILLERY
THE CHIEF OF CONSTRUCTION DIVISION
THE DIRECTOR OF TANK CORPS
THE DIRECTOR OF CHEMICAL WAR SERVICE
THE DIRECTOR OF REAL ESTATE SERVICE
THE BOARD OF ORDNANCE AND FORTIFICATION
THE DIRECTOR OF NATIONAL DEFENSE
THE CHIEF OF MOTOR TRANSPORT CORPS
THE CHIEF OF TRANSPORTATION SERVICE
THE CHIEF OF FIELD ARTILLERY
THE CHICKAMAUGA AND CHATTANOOGA PARK COMMISSION
THE GETTYSBURG PARK COMMISSION
THE SHILOH NATIONAL MILITARY PARK COMMISSION
THE VICKSBURG NATIONAL MILITARY PARK COMMISSION

WASHINGTON
GOVERNMENT PRINTING OFFICE
1920

McAnneny, John Henry.
McKenna, Joseph Edward.
Nerling, Gustave.
Ortiz, Julius.
O'Toole, Frank Codman.
Peak, George Francis.
Pruett, George.
Reid, Robert Lincoln.
Scott, Robert James.
Slipp, Clarence.
Stanton, Jufilson Horatio.
Vandermeer, John William.
Vanelli, Arthur Nicholas.
Veteto, Gus Robert.
Vieira, Leopold Joseph.
Wanless, Frank B.
Heine, John Joseph.
Hill, Warren Arthur.
Holmes, Harrison Stephen.
Almar, Bertram Hillard.
Crews, Millard.
Dawson, Harvey Allen.
Fink, Herbert Jacob.
O'Neill, Nick Persian.
Evans, Hugh John.
Holziner, Carl Peter.
Warren, Robert Flagg.
Whipp, Raymond Calvin.
Walker, E. F.
Hickey, Edward John.
Jones, Orlando Lloyd.
Lang, William Norman.
Myers, Fred.
Balbian, Frederick.
Campbell, Verlin Everett.
Micks, Albert.

The following men volunteered for the experiments at San Francisco:

Leggett, James Verna.
Oldham, George W.
Eagan, Estis Theodore.
Harrell, Lewis Roy Kendall.
Toombs, Herbert Edgar Lawrence.
Workman, Lester.
Thomas, Franklyn Forrest.
Bennett, J. C., jr.
Combs, Lester Robert.
Swan, George.
Mulcahey, Daniel Vincent.
Taylor, Christopher Anthony
Lester, Roy.
Le Duc, Antonio Oliver.
Wages, Vern.
Wall, Lewis Edward.
Lind, Clifford Charles.
Crane, Ellis Madison.
Thompson, Arthur Eugene.
Alsott, Charles Benson.
Lipinski, William.
Tomlins, Roy Lee.
Tegerson, William.
Nardoni, A. M.
Miller, Frank A.
Burton, Clyde.
Dulaney, Floyd Marcue.
Eskew, Herman Virgil.
Hammer, Adolph.
Shankle, John Swanson.
Tharp, Robert Herman.
Autry, Charlie Lester.
Breco, Davis.
Casson, Jesse Meredity.
Fisher, Earl.
McLaughlin, Joseph Francis.
Lorenz, Joshua H.
Hickson, Samuel Dewey.
Morrow, Ernest James.
Stephenson, Neato Augusta.
Hearing, Elvin.
Bertelsen, Hans.
Dickenson, Lester William.
Bennett, Ray Ernest.
Howard, Fred Elmer.
Christian, Lester O.
McGaughy, Oscar A.
Morrison, M. C.
Cullison, George A.
Hosey, R. L.

PREVENTIVE MEASURES.

First and last, all preventive measures which seemed logical, either from *a priori* reasoning or because of seemingly good effects claimed for them elsewhere during the year or in previous epidemics, were tried in the Navy.

These included quarantine, daily inspection of personnel and the taking of temperatures, early isolation of the sick, the wearing of face masks and gowns and rigid aseptic technic by attendants upon the sick; the early transfer of patients to a base hospital; the retention and isolation of patients in dispensaries where they could be segregated in small groups instead of being brought into immediate or indirect contact with large numbers of other patients; strict attention to ventilation, relief of overcrowding, use of muslin screens between bunks or hammocks in barracks; prevention of gatherings indoors as much as possible; restrictions on travel, particularly by common car-

rier; the application of nose and throat sprays to those not yet attacked; the use of prophylactic vaccines, the very general and intensive use of educational measures, and the rigid enforcement of sanitary rules and regulations with particular regard to personal hygiene, cleanliness, care of floors and decks, windows, and other ventilating inlets and outlets, mess gear, drinking utensils, drinking fountains and other articles liable to contamination with mouth and nose discharges of patients or carriers. The protection of influenza patients during convalescence, even those having mild attacks, was generally regarded as an important preventive measure. The therapeutic use of serum donated by patients convalescing from influenzal pneumonia was given a somewhat extensive trial in attempts to reduce influenzal pneumonia case-fatality rates.

Speaking in general terms, the history of influenza in the autumn of 1918 shows that the disease spread rapidly and progressively, attacking communities of all sizes regardless of preventive measures put into effect, and regardless of geographical location, climate, weather, nature of the industries, race, density of population, habits of the people, character of housing, habits of diet, social and economic conditions, sanitation, soil conditions, flora and fauna, or routes and modes of travel.

Naval stations varied greatly in size and density of population as well as with regard to geographical location, environment, and the nature of activities carried on. Strong efforts were made at all stations and on board all vessels to prevent the introduction of the disease and to limit its spread by the enforcement of all preventive measures which were practicable under war conditions. Attention was paid universally to sanitation, education of the naval personnel, ventilation, proper care of mess gear, and early treatment of the sick. Relief of overcrowding was possible in some places; in others, not. Under the necessity of fighting the war it was usually deemed impracticable to establish quarantine of any degree or to prevent intercommunication with civil communities and other naval stations. At different stations various special preventive measures were tried, such as vaccines, use of face masks, daily or twice daily use of prophylactic nose and throat sprays, and putting the men into tents.

Epidemic incidence rates, epidemic death rates, and case-fatality rates varied considerably at different shore stations and among different forces afloat, as the statistical data show. Not infrequently certain specific measures which were credited at one station with having prevented the spread of influenza or with having reduced the complications or with having kept case-fatality rates low failed to prove of any value at another station. So many epidemiological factors were or might have been involved in every instance that it is quite impossible to judge what factors were operative at a given station or to what preventive measures low rates could be definitely attributed when they occurred. It may be said, however, that each of the preventive measures enumerated was thoroughly tried, in conjunction with other measures of course, at some one or more stations where the incidence of influenza was high and the epidemic severe. In other words, each particular preventive measure failed in some instances to accomplish recognizable results.

It should be remarked that influenza was regarded as a disease of the respiratory type disseminated by moist discharges from the

mouth and nose, and the preventive measures applied were those which have come to be looked upon as valuable in preventing the spread of any acute communicable disease of the respiratory type. With the exception of absolute quarantine at the United States Naval Training Station, San Francisco, these measures proved of little or no appreciable value in the presence of epidemic influenza.

The experience of 1918 would indicate that a very important preventive measure when confronted with an outbreak of influenza consists in rapidly enlarging existing medical and nursing facilities for the proper care and treatment of the large numbers of persons who will inevitably be attacked regardless of measures planned to prevent the occurrence or spread of the disease.

Quarantine.—Absolute quarantine was imposed at the United States Naval Training Station, San Francisco, on September 23, before the introduction of influenza. All officers, enlisted men, and civilians were recalled and required to remain on the island. All communication with San Francisco and Oakland was discontinued, except to receive supplies and recruits or other men who reported and necessarily had to be received. Precautions were taken to prevent the crews of tugs from approaching persons on the dock closer than 20 feet. All recruits and others who had to be received from the mainland had the pharynx and nasal passages thoroughly sprayed with a 10 per cent solution of silvol and were required to put on gauze face masks before they were allowed to board the tug bound for the island. Upon arrival they were placed in a quarantine camp for several days, during which they wore masks, were sprayed three times a day with silvol, and were required to keep at a distance of 20 feet from each other.

The entire personnel of the station—officers, enlisted men, and civilians—were required to have the pharynx and nasal passages sprayed once daily with a 10 per cent solution of silvol. All drinking fountains were flamed with a gasoline torch, and all telephone transmitters were disinfected twice daily. In barracks each cot was provided with a muslin screen extending around the head and along one side, 30 inches above the level of the cot. A part of the personnel was quartered in tents. Outdoor recreation was provided.

This was not a pure quarantine experiment. The entire personnel was inoculated with three successive doses of a mixed bacterial vaccine administered October 12, 15, and 18, respectively. This vaccine contained per c. c.:

Pfeiffer bacillus, Rockefeller strain	5,000,000,000
Pneumococcus Type I, various strains	3,000,000,000
Pneumococcus Type II, various strains	3,000,000,000
Pneumococcus Type III, one strain	1,000,000,000
Streptococcus hemolyticus, two strains	100,000,000

The three doses were 0.5 c. c., 0.8 c. c., and 1 c. c., respectively.

While quarantine was in effect no case of influenza ocurred on the station, although all other naval stations on the Pacific coast, as well as civilian communities, experienced epidemics during this period. The disease made its first appearance at the station on December 6, 16 days after quarantine was raised.

In the city of San Francisco the primary epidemic began during the week ending September 21, reached its height during the week ending October 5, and subsided rapidly. This epidemic, as indicated

by epidemic death rates, was of about the same duration and severity as those which occurred in Boston, Mass., and Washington, D. C., in spite of the fact that somewhat drastic ordinances and regulations, which included the compulsory wearing of face masks on the street, were adopted; measures which the cities in the East did not see fit to undertake. A rather sharp recurrent epidemic began in the city during the week ending December 14, and the weekly death rate did not reach an approximately normal level until after the week ending March 8, 1919.

At the United States Navy Yard, Mare Island, Cal., very practical precautions were taken as early as September 23 against the introduction and spread of the disease. Absolute quarantine was not feasible but a modified quarantine was ordered. The epidemic in the Mare Island navy yard began October 4, and reached its height in the latter part of the month. The incidence diminished one half in November, but the epidemic period lasted until November 30.

To the absolute quarantine efficiently maintained on Goat Island must be attributed the entire absence of influenza from this training station while all communities in the vicinity were suffering. After free communication was resumed with San Francisco and Oakland on November 21 the disease was introduced, and during the month of December 148 cases of acute bronchitis, 13 of broncho-pneumonia, 4 of lobar pneumonia, and 25 cases of influenza were reported. Doubtless some at least of the cases reported as broncho-pneumonia were true cases of influenza, and judging from the incidence of pneumonic complications at other stations it is altogether probable that at least 100 cases of influenza occurred. The experience at this station seems to show that under exceptional conditions quarantine can be made effective against the introduction of influenza, but that after quarantine is raised the disease will make its appearance with an incidence proportionate to that obtaining at the time in the surrounding territory. Beyond question, life was saved there by the absolute quarantine.

Deaths from influenza and all forms of pneumonia, during the year 1918, occurred at the United States Naval Training Station, San Francisco, as follows:

Week ending—	Influenza (influenzal pneumonia).	Pneumonia.	Week ending—	Influenza (influenzal pneumonia).	Pneumonia.
Apr. 4	.....	1	Oct. 15	.....	.....
July 7	.....	1	Dec. 4	.....	1
Aug. 21	.....	1	Dec. 22	2	1
Aug. 28	.....	1	Dec. 28	1	.....

Unfortunately for epidemiological purposes, the issue was clouded by the fact that the entire personnel received three doses of mixed bacterial vaccine. It is possible, even probable, that such a vaccine would reduce the percentage of pneumonic complications and case-fatality rates in so far as due to secondary invasion by the micro-organisms represented, but the evidence adduced elsewhere indicates that the vaccine would not protect against influenza. This was the experience at the marine barracks, Parris Island, S. C.; at Quantico,

Va.; at the United States Naval Training Camp, Pelham Bay Park, N. Y., and at the United States Naval Training Station, Great Lakes, Ill. Moreover, among 200 men received at the United States Navy Yard, Mare Island, in a draft from the United States Naval Training Station, San Francisco, at 9 p. m., December 5, three of them were found ill with influenza at 8 a. m., December 6, and during the evening of the same day three additional cases were discovered. On the following day 16 cases developed, making a total of 22, or 11 per cent of the draft, attacked in about 48 hours. This is of interest in connection with the San Francisco experiments discussed on page 422.

It was the opinion of medical officers at the station that spraying of the nose and throat could be eliminated as preventing the disease, because it was used before, during, and after the appearance of influenza cases.

A modified quarantine was imposed at many naval stations. Invariably this measure failed to prevent the introduction of influenza. Influenza proved to be so highly communicable that nothing short of absolute quarantine appeared to have any effect whatever upon the incidence of the disease. At some stations where liberty was restricted and communication with outside sources was reduced to a minimum the epidemic was severe and the attack rate high, while other stations where similar measures were adopted escaped lightly.

The United States Naval Training Camp at Pelham Bay Park furnished an example of the apparent futility of preventive measures in influenza. This station was planned and built in accordance with modern ideas along the lines of preventive medicine. The barracks were comfortable and well ventilated and the men were quartered in comparatively small units. There was a well appointed and well administered detention camp, with separate dispensaries and mess halls. A modified quarantine was in effect at the station. In spite of this the attack rate, the epidemic death rate, and the case-fatality rate were all considerably higher than at the Federal rendezvous, a large armory in a thickly settled section of Brooklyn, N. Y., where the complement was constantly shifting, and where the crew of 1,700 men was berthed in a single large room. No restrictions whatever were imposed on visiting and liberty, because it was not practicable to do so. According to all the tenets of epidemiology this station should have suffered worse than the training camp at Pelham Bay Park, situated at the extreme edge of the city limits in a more or less isolated position.

Vaccines.—Experiments in prophylaxis were conducted at various naval stations almost from the beginning of the severe epidemics in the fall of 1918, with vaccines made from pure cultures of the Pfeiffer bacillus; with hemolytic streptococcus and with mixed vaccines containing the three fixed types of pneumococci and several strains of Type IV pneumococci with or without streptococci or Pfeiffer bacilli. Experiments with the Pfeiffer bacillus lead to the conclusion that no protection against influenza was afforded by bacterins prepared from strains of this microörganisms recovered from the lungs in cases of influenzal pneumonia. Altogether, many thousands of men were vaccinated, with the inevitable result that much conflict of opinion arose from the fact that many individuals vaccinated were not subsequently attacked by influenza. Unless prop-

erly controlled, vaccination experimnts were without value. In the following instances controls were used: Five hundred and fifty-four men in the "incoming detention camp" at the training camp, Pelham Bay Park, N. Y., were given three inoculations of a Pfeiffer bacillus vaccine prepared at the United States Naval Hospital, Chelsea, Mass., and administered in three successive doses, 0.5 c. c., 1 c. c., and 1. c. c. of a well clouded but not counted bacterin. The third inoculations were completed October 5, 1918. On October 10, the 554 inoculated men, together with 800 controls, who had also been held in the incoming detention camp, were released into the main camp. At the time of their release the incidence of influenza in the main camp was decidedly on the decrease and opportunity to contract infection was less than at the height of the epidemic. Nevertheless, 50, or 9 per cent, of the vaccinated men contracted the disease, while only 40, or 5 cent, of the controls became infected.

Several thousand men were vaccinated at the marine barracks, Parris Island, S. C., in the latter part of October; some with a Pfeiffer bacillus vaccine prepared at the United States Naval Laboratory, Philadelphia, Pa., and some with a similar bacterin which included strains of the Pfeiffer bacillus recovered from patients in the United States Naval Hospital, Chelsea, Mass., prepared at the Hygienic Laboratory, Washington, D. C. Many of the men inoculated were transferred overseas shortly afterwards, and their subsequent histories could not be ascertained. However, a draft of 756 men transferred from Parris Island, S. C., in the early part of November came under observation at the marine barracks, Quantico, Va. Of these, 304 had not been vaccinated, and 39, or 12.8 per cent, contracted influenza within a week after arriving at Quantico. Four hundred and fifty-two men of this draft had received from one to four inoculations of Pfeiffer bacillus vaccine while at Parris Island, and 72, or 15.9 per cent, contracted influenza as follows:

After one inoculation, 11 of 75 men (14.6 per cent) contracted influenza.
After two inoculations, 30 of 226 men (13.2 per cent) contracted influenza.
After three inoculations, 8 of 57 men (14.0 per cent) contracted influenza.
After four inoculations, 23 of 94 men (24.4 per cent) contracted influenza.

A study of the severity of the disease in those not vaccinated, in comparison with those who had received vaccine, indicated that vaccination had no marked influence upon the course and severity of the attack. This conclusion was based on observation of 200 cases of influenza in men who had recently arrived from Parris Island, S. C. The findings were as follows:

Number of cases with no prophylactic inoculation	92
Number of cases with one inoculation	29
Number of cases with two inoculations	40
Number of cases with three inoculations	9
Number of cases with four inoculations	30
Total number of cases	200
Mild cases:	
No vaccine	47
With vaccine prophylaxis	57
Total cases	104

Moderate cases:

No vaccine	34
With vaccine prophylaxis	44
Total cases	78

Severe cases:

No vaccine	7
With vaccine prophylaxis	11
Total cases	18

Observation of 281 influenza patients treated in the United States Naval Hospital, Philadelphia, Pa., between October 6 and October 26, 1918, 60 of whom had previously been vaccinated with Pfeiffer bacillus bacterin and 221 not, seemed to show that the incidence of pneumonic complications was decidedly lower in the vaccinated cases. No trustworthy evidence was presented that Pfeiffer bacillus vaccine had any value as a therapeutic agent.

A streptococcus vaccine was used extensively in the thirteenth naval district where responsibility for pulmonary complications and deaths was attributed principally to the microörganism from which the bacterin was prepared. At first regarded as an ordinary hemolytic streptococcus this microörganism was later found to have characteristics similar to those of the Mathers coccus as mentioned above in reference to microörganisms associated with influenzal pneumonia.

The following table indicates the results obtained by the use of this vaccine which was prepared from microörganisms isolated from the blood of living patients and from the tissues in fatal cases. Cultures were nearly always pure. The microörganism could be obtained from the sputum of almost any case and was practically always found in the lung tissues at post-mortem examination. The microörganism easily lost its virulence and hemolytic properties on subculture at 37 C. and was sometimes indistinguishable from a diplococcus. Proof that there was but a single strain was not furnished and it is not unlikely that the vaccine contained more than one strain. Three doses were administered 48 hours apart, 0.5 c. c. (250,000,000), 1 c. c. (500,000,000), and 1 c. c. (500,000,000).

	Complement.		Cases.		Per cent attacked.		Deaths.		Case-fatality percentage.	
	Vaccinated.	Unvaccinated.	Vaccinated.	Unvaccinated.	Vaccinated.	Unvaccinated.	Vaccinated.	Unvaccinated.	Vaccinated.	Unvaccinated.
Philadelphia unit	131	855	37	108	28.2	19.6	0	21	0	12.5
Seattle Training Camp No. 1	.....	4,159	.....	813	.....	19.5	.....	33	.....	4.0
Seattle Training Camp No. 2	602	.....	11	.....	1.60	.....	0	.....	0	.....
Seamen's barracks, Puget Sound	2,800	3,472	57	428	2.03	12.3	0	42	0	9.8
Marines, Puget Sound Navy Yard and ammunition depot	425	.....	5	.....	1.2	.....	0	.....	0	.....
Filipino unit	111	.....	2	.....	1.8	.....	0	.....	0	.....
Aviation unit	83	.....	32	.....	38.5	.....	0	.....	0	.....

It should be said that no unit was divided into two parts for the purpose of running experimental subjects and controls side by side. Circumstances did not permit. In the largest unit (seamen's bar-

racks) many cases of influenza had already occurred before vaccination could be performed; how many is unknown. The same is true of the draft from Philadelphia, but not of the rest of the command.

Conditions of exposure were not materially different in the different units. Housing conditions differed in that some men were in barracks and some in tents, but this seemed to have no effect upon the incidence of the disease. All of the marines were in barracks, rather closely quartered. All of the Seattle Training Camp men were quartered in tents, two men to a tent (8 by 10).

Of 4,212 men who were vaccinated not one man died. Among 111 Filipinos isolated and vaccinated early, and later exposed, there occurred only 2 cases. Among 361 marines vaccinated early, with no attempt to control exposure, there occurred 2 cases, both patients coming down after the first injection. Among 62 marines at the ammunition depot who were vaccinated early there occurred 3 cases—2 after the first injection and 1 after the third. Among 662 sailors at the Seattle training camp, 3 men developed the disease after the first injection, 1 after the second injection, and 7 after the third. Among 83 of the aviation corps there occurred 32 cases, 31 of the patients coming down within a few hours after the first injection and 1 after the third injection. Thus, altogether there were 1,279 men who were vaccinated either before exposure or about the time they were exposed, and of these, 94 developed the disease before vaccination was completed, and 11 afterwards. All recovered. Some of the cases in vaccinated men were fairly severe, and from the blood of one of these patients the diplo-streptococcus mentioned was recovered.

The period of observation was from September 17 to October 21, 1918. Up to November 3 there had occurred but 40 additional cases at the Seattle training camp and 16 at the Puget Sound navy yard, facts which seem to indicate that the epidemic was practically over at the time these data were obtained.

Mixed vaccines were tried at several different stations, but satisfactory controls were not used and war conditions made it impossible to keep track of many of the men vaccinated. The same is true of men inoculated with vaccine composed of the three fixed types of pneumococci. The use of a mixed vaccine at the United States Naval Training Station, San Francisco, Cal., while the station was under absolute quarantine has already been mentioned.

Face masks.—The wearing of face masks by healthy persons was made compulsory at several stations and on board a few vessels. On the whole this was not a practicable measure and little or no good was accomplished by the use of masks. The eyes were not protected. The masks quickly became soiled and required frequent adjustment by the fingers.

Reference has already been made to the three naval air stations in the third naval district, where masks were worn. The attack rates and epidemic death rates were comparatively high at two of them and at the third an epidemic had occurred in the spring.

On board one of the transports all troops and the entire crew were required to wear masks throughout the trip to Europe. The incidence of influenza was very low during the trip and this was attributed by the medical officer very largely to the wearing of masks.

However, other transports in the convoy, sailing from the same port at the same time also had very little influenza on that trip without resorting to masks, although the incidence had been high during the previous trip.

No evidence was presented which would justify compelling persons at large to wear masks during an epidemic. The mask is designed only to afford protection against a direct spray from the mouth of a carrier of pathogenic microörganisms; and assuming that it affords such protection, the probability that the microörganisms will eventually be carried into the mouth or nose by the fingers is very great if the mask is worn for more than a brief period of time. Masks of improper design, made of wide-mesh gauze, which rest against the mouth and nose, become wet with saliva, soiled with the fingers, and are changed infrequently, may lead to infection rather than prevent it, especially when worn by persons who have not even a rudimentary knowledge of the modes of transmission of the causative agents of communicable diseases.

On theoretical grounds it is good practice to require those who visit, examine, or wait upon the sick to wear masks. The experience at the United States Naval Hospital, New London, Conn., was typical of that encountered at several other hospitals. "Face masks were worn constantly by medical officers, nurses, and hospital corpsmen while they were in the wards." "The morbidity rate, nevertheless, was very high among those attending the sick, and our experience indicates that if the mask has any value it is simply in preventing an overwhelming dose of infection from direct coughing or other acts accompanied by forcible expulsion of nose and throat secretions." "While it may be taken for granted that masks should be worn by medical officers, nurses, and hospital corpsmen in handling the sick, our observations lead to the opinion that the use of masks in barracks is not a practicable measure of value under ordinary routine conditions." "The very high infectivity of this disease was demonstrated by results in our contagious annex, which is a building especially constructed for the care of communicable diseases." "During the past four months patients ill with such diseases as cerebro-spinal fever, diphtheria, measles, mumps, scarlet fever, and German measles have been treated in this building." "Upon occasion, all of these different diseases have been handled at the same time, and the patients have been subsisted from the same diet kitchen, and yet there has been no instance of cross infection." "It may therefore be concluded that the technique was satisfactory; nevertheless, it failed to prevent cross infection in the case of influenza." "A number of medical officers and nurses were infected in that building, and the incidence of the disease was just as high there as in the improvised wards."

At the United States Naval Training Station, Great Lakes, Ill., of 674 hospital corpsmen and volunteers of other ratings who were on duty caring for the sick during the epidemic, 96 wore guaze masks. The others did not. Of the latter, 7.9 per cent developed influenza, while 8.3 per cent of those who wore masks contracted the disease. It will be noted that the attack rate in both groups was much lower than for the personnel in general at the station.

Prophylactic nose and throat sprays.—Nose and throat sprays of various kinds were used at several stations and on board many

vessels, not only as a measure applied to the entire personnel in an attempt to prevent the introduction of influenza, but also to check its spread. Those who made use of sprays in a comprehensive way usually felt that good results were accomplished, but comparative statistics do not show this. So many epidemiological factors were operative in all cases and so many preventive measures were tried in addition to spraying that no definite conclusion can be reached from a review of the evidence as to whether or not any great value can be attached to the use of sprays.

At the navy yard, Philadelphia, Pa., an oil-camphor-menthol spray apparatus was installed in the machinery division and a man was kept on duty constantly to spray the nose and mouth of each employee every two hours. The results were reported as satisfactory beyond expectation. "Only two out of a thousand men contracted the disease." Two grains each of camphor and menthol to 1 ounce of liquid petrolatum was used. The liquid petrolatum was regarded as poor culture material, and furthermore it did not wash out the natural protective secretions.

Dobell's solution or alkaline antiseptic solutions were commonly used. Silvol and argyrol solutions were favorites, and chlorinated sprays were used in many places. Solutions of quinine and of zinc sulphate are also mentioned in reports.

Sprays of various kinds were used in the ninth, tenth, and eleventh naval districts and the medical aid to the commandant was of opinion that the procedure distinctly limited the number of cases. The medicament used seemed to be of less importance than the care with which the spraying was done. Reports from numerous stations indicate that cases began to decline in number and severity after spraying was resorted to. Of course, cases usually declined rapidly in numbers and severity as soon as the peak of the epidemic was reached, even though no special preventive measures were undertaken.

If sprays are used it would seem that they should be mildly stimulating but incapable of inflaming the mucous membranes. A spray which causes the mucous membranes to secrete freely may be useful in aiding mechanical elimination of microörganisms which have gained access to the nose or pharynx, but it should be borne in mind that the use of spray apparatus on a number of men in turn is not without danger of becoming a means of disseminating infection.

Another method of applying a medicament to the mucous membranes for prophylactic purposes, and one quite generally overlooked, apparently, was the administration of urotropin to healthy persons during the epidemic. It was observed by a medical officer of the Navy stationed at Los Angeles, Cal., that among 611 persons living in the city, varying in age from 15 to 60 years, who took 5 grains of urotropin three times a day, influenza was contracted in only one instance, the exception being a man of 50 who was irregular in taking his prophylactic doses. The other 610 persons were said to have been exposed to influenza fully as much as their neighbors, many of whom contracted the disease.

Relief of overcrowding.—Overcrowding was undoubtedly an important factor in contributing to the spread of influenza and particularly to the development of complications. However, epidemic

Exhibit #9

THE PRACTICAL ASPECTS OF QUARANTINE FOR INFLUENZA

By Dr. T. H. Whitelaw

Medical Officer of Health, Edmonton, Alberta

PROBABLY never before has the medical profession been confronted with a more baffling problem than has been presented by the influenza epidemic, both as to its possible prevention and treatment. The apparent futility of practically all measures of prevention, some of which were, at the outset, acclaimed with great assurance by members of our profession, and the failure of any particular line of treatment of the many practised and advocated to be generally recognized and adopted, as being specially advantageous, make it incumbent on one attempting to discuss any phase of the subject to approach it with becoming modesty and diffidence.

Influenza began to appear in Edmonton about October 11th, 1918. From October 15th, by special regulations of the Provincial Board of Health, the disease was made reportable and subject to modified quarantine by placard similar to that used for measles, whooping cough, etc.

Before the disease had become epidemic, the City Board of Health, on October 18th, ordered the closing of all schools, churches theatres, picture shows and all public meetings generally.

The Provincial Board of Health on October 25th passed a resolution ordering every person in the Province of Alberta to wear a mask outside of his or her house or residence, except when necessary to partially remove the mask for the purpose of eating.

This order was continued in force until November 23rd, when it was made optional, after which practically no masks were worn except in hospitals by nurses and attendants. Had this mask order been instituted a few days before the epidemic reached its peak, it would probably have been acclaimed as the chief factor in bringing about the rapid subsidence of the epidemic, but unfortunately for the extravagant claims made in justification of the mask order as a means of prevention, the number of cases of the

disease continued to increase rapidly for some time after the order was enforced, and public confidence in it as a prevention soon gave place to ridicule. It will thus be seen that nothing was neglected which in theory might possibly have prevented the spread of the epidemic, but the apparent futility of all the laudable attempts at control, are indicated by the following figures, which do not include the two hundred and forty-nine non-residents, coming to the city for treatment, of whom over 30 per cent. died.

	Cases reported	Deaths
October	2208	61
November	2323	254
December	1258	76

With this digression, I will now confine myself to the consideration of the quarantine for influenza attempted as one of the means of prevention.

At the outset of the epidemic, some physicians were reluctant to admit that the cases were genuine cases of the so-called "Spanish influenza", but later, when numerous deaths occurred, it became apparent to even the most conservative that the real disease prevalent in the East was actually in our midst with its frightful toll of death.

In spite of the energetic work of the officials of the health department, in promptly following up all reports of physicians, and information derived from all other sources, by placarding premises and establishing quarantine, it is apparent that the number of cases above reported and quarantined did not at any time represent more than 60 per cent. of the actual number of cases in the community. Hundreds of cases, whether a physician was in attendance or not, were of so doubtful or mild a nature as to be regarded as common colds, and as a result, no quarantine or placard could be affixed. The difficulty of establishing an accurate diagnosis in many of the milder cases was the stumbling-block in the way of carrying out quarantine measures efficiently. Many citizens regarded the placard as an injustice, either because they did not believe the diagnosis justified, or because their neighbours were alleged by them to be avoiding quarantine by concealment or evasion. Some physicians began to be careless or indifferent in reporting their cases, because they alleged that other physicians were not reporting their cases, and charges of discrimination were frequently made against the officials of the health department, on

whom the duty of placarding and establishing quarantine devolved. The number of houses to be placarded and quarantined was so great, that the limited staff of health officials was greatly overworked, and all, except two, suffered from and recovered from the disease during the epidemic. To have attempted prosecutions in all alleged and real cases of failure to report the disease on the part of householders or physicians would not in my opinion have been of any practicable benefit, for the reason that no magistrate would be likely to convict on evidence, which, owing to the impossibility of absolute certainty in the diagnosis of most cases, must necessarily be contradictory or at least doubtful.

It did not appear that those who took the most elaborate precautions to avoid the infection enjoyed any greater immunity from attack, than did those who appeared to take no precautions whatever. The maintaining of bodily health by normal living and the avoidance of panic, worry or fatigue, seemed to be the only practical method of combatting the infection. The element of fatigue among doctors and nurses who necessarily had to work long hours, undoubtedly accounted for their tendency to eventually fall victims to the disease, rather than the element of special exposure which their work entailed.

From the above considerations I can only conclude that the quarantine and placarding for a disease of the peculiar nature of influenza is impracticable, and the expenditure of time, energy and money in attempting to carry out such a law appear to be disproportionate to any apparent benefits derived therefrom. The fact that the quarantine imposed was only a modified one, which permitted all except the person or persons affected to enter or leave the premises, has led some physicians to suggest the advisability of making the quarantine a strict one, as is the case in scarlet fever or diphtheria. The practicability of applying strict quarantine to influenza is doubtful, as the following considerations indicate.

In influenza there are many grades of severity, from the severe abrupt onset, followed quickly by dangerous developments, chiefly pneumonia, so-called, to the slight indisposition which resembles a common cold or coryza, and from which it is impossible to distinguish it. The accurate diagnosis of hundreds of cases is therefore very difficult, and many physicians hesitate to pronounce such cases as influenza or to report them as such. For this reason, and also because no physician at all may have been called, many cases of influenza even under our present modified quarantine law remain unreported. To change this to a rigid quarantine would

undoubtedly have a decided tendency to increase this hesitation of physicians to report cases and also add largely to the number of householders, who in their desire to avoid quarantine of any kind, neglect to call in their family physician as long as possible. There is some justification for believing that certain physicians are given a preference, and profit thereby, because they are known to belong to this hesitating class and because fewer placards follow on their trail than on that of the more conscientious physicians, who gave the public the benefit of the doubt by reporting even their doubtful cases as suspicious. Physicians who lack public conscience should undoubtedly be prosecuted, but the difficulty of obtaining a conviction in the case of such a disease as influenza is obvious, and can only be appreciated by the health officer who has attempted such prosecutions under our present laws.

That the disease was much more prevalent and affected a much larger proportion of the people than the worst epidemic of scarlet fever, diphtheria, and smallpox, we are every likely to have, is apparent. Were it similar to the above rigidly quarantined diseases as to its prevalence and method of transmission, nobody could reasonably question the wisdom of applying to it the most rigid form of quarantine. But we do not yet know with absolute certainty all the avenues by which it is transmitted, and to put on a strict quarantine and maintain it effectively against such an insidious and extremely prevalent affection as we now know it to be, if we take into account the great variety of its manifestations, would necessitate an army of inspectors or policemen and a whole fleet of delivery rigs supplying food at the public expense.

In Chicago, notification and isolation of the patient was required, but placards were only affixed to premises where the occupants had been delinquent in obeying the law *re* notification of the health department and isolation of the patient as far as possible. This method is believed to have secured a much better notification of cases than our system of placarding, which appears to penalize those who honestly try to co-operate with the health department, while those who conceal the disease or neglect to report in large numbers, are subjected to no inconvenience and cannot be prosecuted in the majority of cases with any hope of success. The law regarding modified quarantine associated with placarding of the premises, as applied to the minor diseases, German measles, measles, whooping cough, mumps, and more recently influenza, is, generally speaking, more honoured in the breach than in the observance. Can any health officer safely assert that in his municipality any reason-

able proportion of the cases of such diseases are ever reported to his department, where placards are used? To many of such minor affections no physician is called, and there is little doubt that the desire to avoid quarantine and especially the placard, which unfortunately appears to be regarded with so much disfavour, deters many from calling in their physicians. In Edmonton, knowledge of the majority of such cases is derived from the school teachers who report to the health department all children absent from school without proper explanation. Where there are no children of school age, it is quite possible for such minor affections to exist and recover without detection.

To sum up, it is evident, that no public health law, which has not the endorsation and support of the public generally, can ever be reasonably well enforced. Human nature cannot be altered, but laws can be, and it seems desirable that our regulations regarding quarantine should be revised in such a way as to secure the maximum co-operation of the community, including the medical profession, in their enforcement. The apparent success of the method followed in Chicago in connection with influenza cases, suggests that the same method might work out advantageously in many of the minor and less serious infections now placarded under the name of "modified" quarantine, and secure a much more efficient control of these infections by health departments. It would penalize by a placard only those who failed to report and submit to the instructions of health officials, and would thus be a strong incentive in securing the co-operation of the public generally with health departments in the prevention, as far as possible, of the minor infections, which are unfortunately regarded so lightly by the majority of the community in spite of the fact that many untimely deaths result from them.

I am aware that some reasonable arguments can be advanced in support of placarding the minor or modified quarantine infections, but in my opinion the disadvantages of such a measure, from the standpoint of possible prevention and control, far outweigh the advantages. Following the world war, we hear a great deal about co-operation in all lines of human endeavour. Would it not be possible to secure a greater measure of co-operation of all the forces in our community, in obtaining the maximum efficiency in the enforcement of our public health laws, by reorganization and revision of these along the lines of sane and reasonable regulations which are in accord with the latest and most reliable information derived from scientific investigation, experiment and experience?

Exhibit #10

Therapet Foundation (http://www.therapet.org) has provided AAT services at 3 acute care inpatient hospitals (visitation programs), inpatient adult and outpatient children rehabilitation facilities (both goal-oriented therapy and true AAT), and a psychiatric prison in Texas for almost 15 years. Over this period, the Foundation has implemented the great majority of the guidelines outlined in the article, and we applaud the author's efforts to standardize AAT/AAI policies.

We agree with the most of the author's recommendations. We are particularly pleased with the recommendations on shelter animals and serologic testing for rabies antibodies. Based on our experience in the field, we would like to emphasize several points in the article's guidelines.

Two keys to any successful AAT/AAI program are animal selection and animal training. The importance of a well-designed and carefully implemented temperament-testing program for selection of therapy animals cannot be overemphasized. This program must be carefully planned by individuals with expertise in animal training and handling. It should be kept in mind that the American Kennel Club's (AKC) Canine Good Citizen (CGC) program was not designed to be a temperament test for therapy animals.

Training of therapy animals before patient contact is equally as important for patient safety. Every AAT/AAI group needs to implement a formalized training program. This training must be ongoing, as emphasized in the guidelines. Restricting animals from visiting any patients in isolation, as outlined in the guidelines, is an essential aspect of a safe and successful AAT/AAI program. Clearly, the risk to isolation patients greatly outweighs the benefits of patient–animal interactions.

We completely agree with the article's recommendation that each health care facility establish its own policies regarding its AAT/AAI program. We would emphasize that the health care facility should submit these policies for careful review by appropriate facility committees and legal departments before allowing any animals into the facility.

Another important recommendation is that each AAT/AAI group and each health care facility consult with both a physician and a veterinarian to provide guidance on infection control practices and zoonotic issues unique to the facility's geography. This will make establishing and maintaining policies easier and provide safer patient–animal interactions.

The Therapet Foundation applauds the efforts of the working group and its guidelines. We hope that this will provide a first step toward standardizing AAT/AAI programs in North America, as well as encourage renewed emphasis on the need for research into this health care field.

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The standard for the surgical mask

To the Editor:

In their recent article, Oberg and Brosseau[1] described in detail 2 tests used by the Food and Drug Administration (FDA) to determine whether or not to grant marketing approval to surgical mask manufacturers. Other than giving a manufacturer approval and reference to market its product, the significance of the test results to the infection control practitioner do not appear to be relevant to the work done by a host of early clinical investigators.

EARLY TESTING FOR EFFECTIVENESS

The study of Hamilton, published in 1906, focused on the transmission of communicable diseases and the important role of sputum droplets in the dissemination of tuberculosis infection.[2] In 1918, Weaver[3] published the results of his study on the possible role of face masks in preventing the spread of diphtheria, meningitis, pneumonia, and other diseases and introduced the practice of covering both the nose and mouth when providing patient care. That same year, Doust and Lyon[4] examined the role of face masks on transmission of infections of the respiratory tract. They found that speaking without a mask in ordinary conversational tone for 5 minutes projected relatively very few bacteria from the mouth, and only for a distance of 1 to 2 feet. On the other hand, speaking without a mask in a loud tone for 5 minutes generated considerably more bacteria, with 1 organism projecting more than 3 feet. As expected, coughing periodically without the use of a mask for 5 minutes generated the greatest number of bacteria, some of which projected as much as 10 feet.

A year later, Weaver investigated the influence of droplet infection in terms of the distance traveled by mouth droplets that had been driven out in forced respiratory efforts.[5] His findings demonstrated that the distance that the droplets traveled in air depended principally on the force at which they were driven from the mouth, and that small droplets could travel some distance, especially when carried by air currents.

FAILURE OF AN IN VIVO TEST

A massive influenza outbreak in 1919 posed a challenge that led to a policy of compulsory use of face masks to check the epidemic. Because influenza is a droplet-borne infection, this policy was based on sound reasoning, and thus favorable consequences were expected. The actual failure of mask use to prevent the spread of disease was disappointing. Although the masks had been worn cheerfully and universally, state health officials concluded that the masks' filtering capability varied, depending on the number of layers and fineness of the gauze mesh. They also found that when the mask material was sufficiently dense to provide effective filtering, breathing was difficult, and leakage occurred around the edges.[6]

NEW DEVELOPMENTS

Although the initial use of face masks proved ineffective, the effort was not for naught, because these masks were the forerunners to the era of new materials and designs in masks. The first change in the design was disclosed in Walker's study in 1930.[7] In establishing the minimum standards for a mask to be "germ-proof," Walker determined that it should be constructed so as not to permit organisms to pass through it when the wearer, with both nose and mouth covered, talked for 1 hour, with the area in front of the mouth moistened during the last 15 minutes. In addition to including a 6-inch square of rubber (obtained from a discarded surgical glove) in the front area of the mask, he also introduced the use of a small piece of aluminum in the upper part of the mask that could be bent to fit the nose.

THE NEED FOR A "SURGICAL" MASK

Up to this time, attention had been focused on the use of face masks to prevent transmission of respiratory infections. It was generally believed that there was no room for improvement in the operating room technique that had been handed down for several decades, and thus, there was no need to improve the excellent results that were being achieved in wound healing.

Note that Oberg and Brosseau believe that "the FDA should evaluate the use of surgical masks for their original intended purpose of preventing wound infection." To date, the benefit of using face masks in surgery is still not evidence-based. Considering the myriad of variables involved, it remains highly doubtful whether this benefit will ever be demonstrated conclusively.

CONCLUSION

During the early stages of face mask development, filtering efficiency was expressed in terms of actual use conditions. Although the FDA standards do not address the length of time that a mask can be worn and maintain effective filtering capability, a mask's filtering efficiency is contingent on its fit and comfort for the wearer. One manufacturer has recently introduced a new surgical mask whose filtering efficiency has been determined by a "new" standard differing from that used by the FDA and whose performance was determined under laboratory conditions rather than under actual use conditions.

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Improving avian influenza (H5N1) diagnositics: What do we need?

To the Editor:

We read with interest the article by Chen et al[1] and would like to add some comments relevant to improving avian influenza (H5N1) diagnostics. Before 2006, most cases of avian influenza (H5N1) were initially made using rapid influenza tests at the point of care.[2-4] In 2006, the 2-3 sialic acid receptor, a specific receptor for H5N1, was identified in the human lower respiratory tract.[5] The relevance of this finding has been applied to experiences with human case detection of avian influenza (H5N1) in Thailand.

Historically, the rapid surge in clinical cases of H5N1 in 2003 prompted the Thai Ministry of Public Health to stockpile antiviral drugs in H5N1-endemic regions and to establish the Thai National Coordinating Laboratory System (NCLS) for expedited case detection of human infections.[5] The Thai NCLS emphasized field-based training focused on the procurement of multiple deep

Exhibit #11

HISTORY OF SURGICAL FACE MASKS

John L. Spooner

The myths, the masks, and the men and women behind them

It is difficult to determine exactly when face masks were first used to help control surgical sepsis. In 1897 Johann von Mikulicz Radecki[1] described a surgical mask composed of one layer of gauze. That same year Fluegge[2] demonstrated that ordinary conversation could disseminate bacteria-laden droplets from the nose and mouth, substantiating the need for an effective face mask. This marked the realization of the danger of human exhalation as a cause of surgical wound sepsis.

In 1898 Huebner[3] recommended that masks made of two layers of gauze, worn at a distance from the nose, be used during operations. He showed that mask efficiency was improved by increasing the layers of gauze and that masks worn close to the nose collected moisture and decreased in efficiency. In 1905 Hamilton[4] proposed that scarlet fever was transmitted through droplet infection. She recommended that masks be worn by nurses handling sterile dressings and by doctors during surgery because of the danger of droplet infection from the mouth and nose. Lord Moynihan[5] in 1906 also advocated use of masks during operations.

During the next few years, various investigators confirmed the value of face masks in protecting the wearer against infection. In 1915 Meltzer[6] advised that masks of fine mesh gauze be used to cover the faces of patients with infantile paralysis and the faces of personnel attending them. In 1918 Weaver[7] reported that over a two-year period the incidence of diphtheria contracted by attendants of infected patients was reduced to zero after wearing masks of double thickness gauze. It is interesting to note that he recommended sterilization of masks after each use, and replacing a mask with a sterile one when it became moist, and that he cautioned against hands being placed on the mask.

In that same year, Capps[8] followed the procedure of Weaver and confirmed the efficacy of face masks in military hospitals for protecting personnel attending patients with contagious diseases, as well as for protecting patients against cross-infection. Capps

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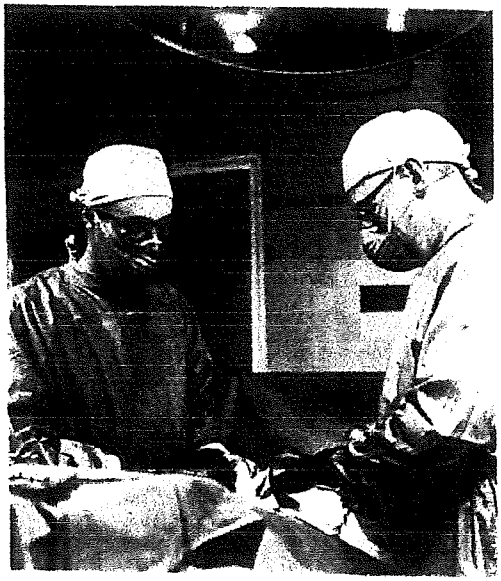

". . . *Today the importance of face masks to help prevent surgical wound infection is universally accepted . . .*"

used a gauze mask of three to four layers, 5″x7″ in size.

At about this same time, various investigators were attempting to determine which type of gauze mask was most effective. The first report on the relative effectiveness of various gauze masks appeared in 1918, shortly after Capps presented his findings. Doust and Lyon[9] tested three types of masks: coarse gauze, medium gauze, and "butter cloth." Each mask was 6″x8″ with hemmed edges, had four-cornered ties, covered from below the chin to above the nose, and varied from two to 10 layers in thickness. They concluded that the coarse gauze was inefficient regardless of the thickness, and that a finer gauze was more efficient.

In 1919 Weaver[10] and Leete[11] confirmed the findings of Doust and Lyon. Weaver found that mask efficiency was in direct ratio with the closeness of the mesh and the number of thicknesses of gauze. He recommended a fine mesh gauze with 44x40 threads to the inch. Leete further confirmed that a wet mask is completely inefficient and also recommended that masks be changed when worn for any length of time.

By the late 1920's, the use of gauze face masks was widespread. Additional data confirming the value of face masks in preventing infection of surgical wounds were published by Walker in 1930, by Meleney in 1935, and by Hart and Davis[12] in 1937. Davis also confirmed that wearing masks over the mouth only is entirely inadequate and that the longer the operation, the greater the risk of contamination.

In the 1930's variations of the gauze type masks began to appear. Walker proposed that a six-inch piece of rubber be placed between two layers of gauze to create a "germproof" mask. Mellinger[13] designed a mask consisting of a 14 karat gold-filled wire frame, covered with waxed paper on both sides, and extending to below the chin. Kaplan[14] designed a similar mask, using washed X-ray film as the deflector material. Blatt and Dale[15] reported that the ordinary gauze mask was both uncomfortable and bacteriologically ineffective compared to their more comfortable, highly effective cellophane, gauze deflection mask. Some of the other deflector-type masks reported on during this period included: the "Jel" mask which was a combination of gauze and filter; a mask with a cellulose derivative, plastacele, and including cotton pledgets; a flannel mask which was a layer of Alaska flannel placed between two layers of 44x40 mesh gauze; and a paper mask consisting of a paper napkin, two small paper clips or safety pins, and two rubber bands.

In 1938 McKhan, Steeger and Long compared the efficiency of gauze masks and deflector-type masks currently in use, and also reported on two new masks.[16] The four masks tested were: 1) absorbing gauze mask; 2) impervious mask which deflected expelled air behind the mask wearer; 3) paper masks; 4) filter mask in which a compressed layer of cotton was placed between layers of absorbing gauze. The filter

type of mask proved to be the most effective of all, effective for a longer period, and effective after repeated washings.

With the introduction of antibiotics in the 1940's, and their rapid acceptance as a means of controlling infection, interest in surgical masks decreased. There were no new developments and no papers of significance were published. However, as the years went by and clinical data accumulated, it became apparent that the "wonder drugs" were no substitute for meticulous attention to aseptic surgery techniques.

In the late 50s there was renewed interest in surgical masks that would effectively protect the patient's open wound from the discharge of pathogens from the mouth and nose of operating room personnel. Aseptic surgical technique now included the surgical scrub, rubber gloves, capping and gowning, and sterile drapes. Airborne bacteria remained as one of the significant factors influencing the rate of surgical wound sepsis.

In 1958 Kiser and Hitchcock reported on a mask that combined the deflection and filtration principles.[17] This was a plastic mask that diverted the flow of breath backward on either side. Filter material near the side outlets was designed to trap the deflected organisms. The next year Adams[18] evaluated a fitted filter mask and found it more efficient than gauze masks. In 1960 Rockwood and O'Donoghue[19] judged that the length of time a filter mask retains its efficiency was three hours; confirmed the inefficiency of absorbing gauze masks; and stressed the fact that the proper use of the best mask available could prevent infection.

In 1961 Musselman[20] reported on a new fitted mask designed to be used only once and then discarded. The mask incorporated a filter in a plastic shell that was shaped to fit the face. An elastic band secured it in place. Excellent bacterial filtration was reported.

A great deal of work has been done to evaluate the efficiency of face masks. Studies by numerous investigators confirm that gauze masks are of negligible efficiency, multiple layers must be used, coarse and medium mesh are completely inadequate, dampening further decreased efficiency, improper fitting permitted bacteria to escape from beneath the sides of the masks, and that they were most uncomfortable to wear.

". . . The longer the operation, the greater the risk of contamination . . ."

In general, deflector-type masks are reported as inadequate because they only prevent the exhalation of bacteria directly in front of the wearer's mouth. The number of colonies of bacteria throughout the room remain the same regardless of whether or not a mask is worn.

Rockwood and O'Donoghue and Adams et al best summarize the inefficiency of gauze masks for protecting the patient or his open wound against germs exhaled by operating room personnel. "For many years, the traditional gauze mask has been worn in recognition of this problem and as one attempt at solution. Unfortunately, gauze masks are of negligible efficiency. . . . There is a discernible barrier effect directly in

front of a dry gauze mask and, more noticeably, in front of doubled dry gauze masks for short periods of time after they are put on. This protective effect diminishes rapidly as the mask becomes moist, is related to the amount of talking or forcefulness of breathing, and is down to less than 10 per cent efficiency after ten minutes if the wearer is also talking. However, there is a billowing-out effect around the sides of these masks from the beginning of wearing, no matter how carefully they are applied."[21] "Maximum mask efficiency is dependent upon an adequate peripheral fit as well as efficient filter material."[22] A mask with high filtration efficiency must make tight and non-leaking contact with the skin of the wearer to be of clinical value. When masks do not fit properly, or billow out, "one can gather large numbers of bacterial colonies from air emerging beneath the sides of these masks from the moment they are put on."

"The filter-type mask is the most efficient and to wear a mask of absorbing gauze, especially of wide, coarse gauze, means poor protection to the patient. Many hospitals are using and buying improper masks. Since we have standards of sterile techniques in hospitals, it would be of benefit to the hospitals to have a standard setup for masks, in order that absorbing masks of coarse gauze and improper thread count are not used."[23]

As noted above, the ability of a surgical mask to filter efficiently also involves the length of time it can maintain that efficiency. Even earlier investigators recognized that a wet mask becomes completely inefficient, and rcommended that all masks be changd after being worn for any length of time. The adverse effect of moisture and of prolonged wearing periods on the efficiency of many masks has also been emphasized by others.

Today the importance of face masks to help prevent surgical wound infection is universally accepted. Adams et al believed that "Air contamination of a room by human exhalation is at least 98 per cent preventable and controllable by proper filter masking of all people entering the room." New and improved methods for evaluating the effectiveness of face masks play an important role by helping determine the best possible mask available.

Most evaluation methods utilized agar plates, petri dishes, or glass slides exposed at various distances to the source of droplets to catch and determine contaminated particles. In 1942 Jennison attempted to measure orally expelled contaminents by means of high-speed photography.[24] Musselman also employed high-speed photography and stroboscopic lighting in a sneeze test to demonstrate the superior performance of a fitted filter mask compared to gauze masks. Hirshfield and Laube[25] developed an experimental chamber designed to achieve controlled environmental and quantitative sampling of bacterial contaminents. In 1958 Andersen[26] developed a sampling chamber to collect airborne particles in several categories of decreasing particle size. More recently Green and Vesley[27] pointed out that "Critical studies of mask efficiency which employed artificial aerosols yielded valuable information about the filtering capacity of masks, but did not simulate the normal orally expelled microflora and the saliva droplets in which they are incorporated. Consequently, most of the mask efficiency ratings which are available in the literature are not directly related to actual practical conditions." They recommend a mask evaluation method that would provide "information which is both volumetric in nature and which approximates the actual conditions under which a mask is worn."

During the last decade growing concern with postoperative infections has intensified interest in masking. The incidence of surgical wound infections in hospitals is reported to have risen appreciably." New surgical procedures that permit operations of greater magnitude, duration and trauma increase the

potential for such infections. It has been stated that "every major infection costs someone $3,000. An infection rate of 50 per 1,000 or 5 per cent, which equals $150,000 per 1,000 cases, has been reported in some series."[28]

A 5 per cent rate of infection, projected against a base of 25 million surgical procedures in the United States annually, totals an estimated 1.25 million cases, at a calculated cost of over $3 billion.

"One should also consider such factors as morbidity and mortality, costly and prolonged hospitalization, additional and complicated treatment and loss of time and money. Infections slow bed turnover in overcrowded hospitals, and compensation claims raising the question of potential liability of the hospital and the physician, are a frequent sequel."[29]

Every effort to strengthen the links of aseptic technique should be made. Even a one per cent reduction in the rate of infection reduces the estimated U.S. total by 250,000 cases; ten per 1000; one per 100 procedures.

With new medical care programs bringing a further increase in the number of patients over the age of 65, operations of greater magnitude and duration, a shortage of nursing personnel, and increasing costs of patient care and bed space, the contribution of an efficient surgical mask to help prevent wound infections is of importance. It is the perpetual responsibility of both manufacturers and the medical community to evaluate new materials, products and procedures which can make possible a reduction in the rate of infection.

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Exhibit #12

Mask-wearing and respiratory infection in healthcare workers in Beijing, China

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ABSTRACT

Objectives: The aim of the study was to determine rates of mask-wearing, of respiratory infection and the factors associated with mask-wearing and of respiratory infection in healthcare workers (HCWs) in Beijing during the winter of 2007/2008. Methods: We conducted a survey of 400 HCWs working in eight hospitals in Beijing by face to face interview using a standardized questionnaire. Results: We found that 280/400 (70.0%) of HCWs were compliant with mask-wearing while in contact with patients. Respiratory infection occurred in 238/400 (59.5%) subjects from November, 2007 through February, 2008. Respiratory infection was higher among females (odds ratio [OR], 2.00 [95% confidence interval {CI}, 1.16-3.49]) and staff working in larger hospitals (OR, 1.72 [95% CI, 1.09-2.72]), but was lower among subjects with seasonal influenza vaccination (OR, 0.46 [95% CI, 0.28-0.76]), wearing medical masks (reference: cotton-yarn; OR, 0.60 [95% CI, 0.39-0.91]) or with good mask-wearing adherence (OR, 0.60 [95% CI, 0.37-0.98]). The risk of respiratory infection of HCWs working in low risk areas was similar to that of HCWs in high risk area. Conclusion: Our data suggest that female HCWs and staffs working in larger hospitals are the focus of prevention and control of respiratory infection in Beijing hospitals. Mask-wearing and seasonal influenza vaccination are protective for respiratory infection in HCWs; the protective efficacy of medical masks is better than that of cotton yarn ones; respiratory infection of HCWs working in low risk areas should also be given attention.

Keywords: masks; respiratory tract infections; health personnel.

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INTRODUCTION

Influenza pandemic has been a global public health issue in recent years,[1] and in 2009, a pandemic of a novel H1N1 influenza virus of swine origin occurred.[2,3] During the initial stages of an influenza pandemic, supplies of vaccines and antiviral medications are likely to be delayed or inadequate to treat a very large number of affected individuals. Therefore, non-pharmacological interventions will be important, including the use of respirators and/or medical masks, which is able to confer respiratory protection.[4-6] If hospitals are to continue to function adequately during a pandemic, reliable access to effective protection strategies for healthcare workers (HCWs) will be imperative. Reducing transmission to HCWs may not only help support the healthcare workforce, but may also prevent influenza transmission to patients.[7]

It is commonly acknowledged that adherence with an intervention can change with perception of risk during a pandemic or an outbreak of unknown origin. Since the epidemic of SARS in Beijing in 2003, awareness and commitment to infection control increased, including the use of masks among HCWs. However, we are not aware of the exact rate of and adherence to mask-wearing after the SARS outbreak in 2003. Furthermore, we commonly assume that frontline HCWs are at increased risk of respiratory infection, but to the best of our knowledge there is no data examining this in our setting. Therefore, the purpose of our study was to determine the level of mask-wearing and respiratory infection in healthcare workers during an influenza season in Beijing, China.

METHODS

Subjects and survey design

Between April 20, 2008 and May 15, 2008, we undertook a survey to examine the level of mask-wearing and respiratory infection in HCWs from eight hospitals, in Beijing, China. If we assumed that the proportion of HCWs

with good mask-wearing adherence (wearing the mask for ≥ 70% of patient-contact time) was equal to 50%, a 5% precision, with a 95% confidence interval according to the formula stated by Daniel,[8] the required sample size for this survey would be 384 HCWs. Eventually, 400 HCWs were enrolled. These 400 HCWs came from a range of different departments and wards representing high and low risk settings for respiratory infection (respiratory, emergency, infectious disease and surgical departments) of eight hospitals in Beijing, using a two-stage random sampling technique. For this study, we classified the first three wards/departments as being high-risk settings for respiratory pathogen transmission and the surgical department as being low risk. In the first stage, eight hospitals were randomly selected from 23 level 2 or 3 hospitals in Beijing. In China, hospitals are categorized into three levels (Level 1, 2 and 3) according to the magnitude (Level 3 > Level 2 > Level 1).[9] In the second stage, for each selected hospital, 50 subjects were randomly enrolled in this survey from respiratory, emergency, infectious disease and surgical departments.

Data collection

Using a standardized questionnaire, we developed a survey that assessed: demographic characteristics; professional designation and clinical duties; attitude and adherence to mask-wearing, mask types used; hand washing frequency, seasonal influenza vaccination; and respiratory infection (clinical respiratory illness [CRI], defined as having at least two of the following symptoms simultaneously: fever, cough, sore throat, nasal congestion or rhinorrhea)[10] during the 2007/2008 (from November, 2007 through February, 2008) influenza season.

Attitude to mask-wearing was assessed by asking the following question: Do you think it is necessary to wear masks when in contact with patients? Attitude was categorized as active (necessary to wear masks when in contact with patients) and not active (not necessary to wear masks when in contact with patients).

Mask-wearing adherence was measured by the following question: for what percentage of patient-contact time did you wear a mask or respirator? According to expert opinion, adherence was categorized as good (wearing the mask for ≥ 70% of patient-contact time) and poor (wearing the mask for < 70% of patient-contact time).

Hand washing frequency was assessed by asking the following question: Do you think it is necessary to wash hands after contact with each patient? Frequency was categorized as frequent (necessary to wash hands after contact with each patient) and not frequent (not necessary to wash hands after contact with each patient).

Statistical analysis

Questionnaire data were entered in duplicate using EpiData Software, and data were analyzed using SPSS 11.5 statistical package (SPSS Inc., Chicago, Illinois, USA). Univariate and multivariate logistic regression analyses were conducted to determine predictors of mask-wearing adherence and respiratory infection in HCWs. Predictive factors were first analyzed by univariate analysis, and then factors with p-values < 0.5 or those that were thought to be clinically significant by professional view were included in the multivariable model; backward logistic regression was conducted by removing variables with p > 0.1. For all statistical analyses two-tailed tests were used, and statistical significance was defined as $p < 0.05$.

RESULTS

Subject characteristics

All 400 subjects selected for this survey participated in and completed the study. The median age was 35 years and about 81% (324/400) were female. About 47.8 % (191/400) were doctors, and 52.2% (209/400) were nurses; 52.7% (211/400) were classified as being in a junior role, and 80% (320/400) were working in high-risk settings. About 28.5% (114/400) reported having taken seasonal influenza vaccination. Detailed demographic characteristics of the subjects are reported in Table 1.

Mask use and respiratory infection in subjects in seasonal influenza season

All subjects (100%) reported mask use. The majority (70%, 280/400) of participants self reported good adherence with masks. About 84.0% (336/400) reported adverse effects of mask-wearing, and 43.0% (172/400) reported more than two adverse effects (Table 2). The most commonly reported adverse effect was breathing difficulties (56.5%, 226/400). The washable, reusable cotton-yarn mask was the most common type of mask used as reported by participants (59.8%, 239/400), followed by medical masks (40.2%, 161/400). Close to 60% of participants reported having had clinical respiratory illness (59.5%, 238/400) during the influenza season. (Table 2).

Predictors associated with mask use adherence

Multivariate analysis showed that good mask-wearing adherence was higher among females (odds ratio [OR], 3.34 [95% confidence interval {CI}, 1.77-6.33; $p < 0.001$), level 3 hospital (reference: level 2; OR, 2.61 [95% CI, 1.52-4.49]; p= 0.001), high risk department (reference: low risk; OR, 2.05 [95% CI, 1.06-3.97]; p = 0.033), intermediate level (reference: senior level; OR, 2.55 [95% CI, 1.10-5.91]; p = 0.029) and junior level (reference: senior level; OR, 2.77 [95% CI, 1.23-6.24]; p = 0.014), active attitude to mask-wearing (OR, 12.25 [95% CI, 6.13-24.50]; $p < 0.001$) and frequent hand-washing (OR, 2.06 [95% CI, 1.20-3.54]; p = 0.009) (Table 3).

Table 1. Demographic characteristics of the subjects

Characteristic	Total (n = 400)	
	Number	Percentage (%)
Gender		
Male	76	19.0
Female	324	81.0
Age group (years)	Median: 35 years	
< 30	128	32.0
30-40	176	44.0
> 40	96	24.0
Occupation type		
Doctor	191	47.8
Nurse	209	52.2
Level of profession		
Junior	211	52.7
Intermediate	140	35.0
Senior	49	12.3
Setting*		
Low-risk	80	20.0
High-risk	320	80.0
Seasonal influenza vaccination		
Yes	114	28.5
No	286	71.5

*Respiratory, emergency and infectious disease departments were classified as being high-risk settings for respiratory pathogen transmission, and surgical department as being low risk.

Table 2. Mask-wearing and respiratory infection in the subjects

Characteristic	Total (n = 400)	
	Number	Percentage (%)
Mask-wearing adherence*		
Good	280	70.0
Poor	120	30.0
Mask type		
Cotton-yarn mask	239	59.8
Medical mask	161	40.2
Adverse effects		
Any adverse effect	336	84.0
Difficulty breathing	226	56.5
Discomfort	204	51.0
Allergy	95	23.8
Pain	43	10.8
≥2 adverse effects	172	43.0
Respiratory infection‡		
Yes	238	59.5
No	162	40.5

*Mask-wearing adherence was categorized into two groups: good adherence (wearing the mask for ≥ 70% of patient-contact time) and poor adherence (wearing the mask for < 70% of patient-contact time).
‡Defined as having at least two of the following symptoms simultaneously: fever, cough, sore throat, nasal congestion or rhinorrhea.

Predictors associated with respiratory infection

Multivariate analysis showed that females (OR, 2.0 [95% CI, 1.16-3.49]; p = 0.013) and staff working in level 3 hospitals (reference: level 2; OR, 1.72 [95% CI, 1.09-2.72]; p = 0.02) were at increased risk of respiratory infection. But subjects with seasonal influenza vaccination (OR, 0.46 [95% CI, 0.28-0.76]; p = 0.002), wearing medical masks (reference: cotton-yarn; OR, 0.60 [95% CI, 0.39-0.91]; p = 0.018) or with good mask-wearing adherence (reference: poor; OR, 0.60 [95% CI, 0.37-0.98]; p = 0.041) were at lower risk. The risk of respiratory infection of HCWs working in low risk areas was similar to that of HCWs in high risk areas (Table 4). Although frequent hand-washing was a protective predictor for respiratory infection (OR, 0.65 [95% CI, 0.43-0.97]; p = 0.034) in univariate analysis, this action was not associated with respiratory infection in multivariate analysis.

DISCUSSION

In our study, we found high self-reported mask adherence, despite the majority of HCWs having reported adverse effects of mask-wearing. This high level of mask-wearing adherence may be attributed to enhanced management of nosocomial infection control and improved consciousness among HCWs following the SARS outbreak in Beijing in 2003, especially after the occurrence of SARS infection in HCWs.[11] We found that the majority of our participants used re-usable cotton-yarn masks, followed by medical masks. N95 masks were not reported as being used routinely. It may be hypothesized that the cost of N95 masks may be a potential barrier for their use in these wards, and departments prefer to re-usable cotton-yarn masks which could be considered as more economically viable in the setting of limited funding/resources.

Table 3. Predictors of mask-wearing adherence among healthcare workers

Variable	Mask-wearing adherence*		Univariate analysis		Multivariate analysis	
	Poor	Good	OR (95% CI)	p-value	OR (95% CI)	p-value
Gender						
Male	44	32	Ref		Ref	
Female	76	248	4.49 (2.66 - 7.57)	**< 0.001**	3.34 (1.77 - 6.33)	< 0.001
Age						
< 30	28	100	Ref			
30-40	49	127	0.73 (0.43 - 1.24)	**0.239**		
> 40	43	53	0.35 (0.19 - 0.62)	**< 0.001**		
Hospital level[#]						
Level 2	77	123	Ref		Ref	
Level 3	43	157	2.29 (1.47 - 3.55)	**< 0.001**	2.61 (1.52 - 4.49)	0.001
Department[†]						
Low risk	39	41	Ref		Ref	
High risk	81	239	2.81 (1.69 - 4.65)	**< 0.001**	2.05 (1.06 - 3.97)	0.033
Occupation						
Doctor	77	114	Ref			
Nurse	43	166	2.61 (1.68 - 4.06)	**< 0.001**		
Level of profession						
Senior	27	22	Ref		Ref	
Intermediate	43	97	2.77 (1.42 - 5.40)	**0.003**	2.55 (1.10 - 5.91)	0.029
Junior	50	161	3.95 (2.07 - 7.54)	**< 0.001**	2.77 (1.23 - 6.24)	0.014
Active attitude to mask-wearing[‡]						
No	55	15	Ref		Ref	
Yes	65	265	14.95 (7.95 - 28.13)	**< 0.001**	12.25 (6.13 - 24.50)	< 0.001
Seasonal influenza vaccination						
No	90	196	Ref		Ref	
Yes	30	84	1.29 (0.79 - 2.09)	**0.31**		
Frequent hand-washing**						
No	73	128	Ref		Ref	
Yes	47	152	1.84 (1.19 - 2.85)	**0.006**	2.06 (1.20 - 3.54)	0.009
Patient-contact time						
< 6 h per day	26	29	Ref			
≥ 6 h per day	94	251	2.39 (1.34 - 4.28)	**0.003**		
Adverse effects of mask-wearing						
No	20	44	Ref			
Yes	100	236	1.073 (0.60 - 1.91)	0.812		
Mask type						
Cotton-yarn	69	170	Ref			
Medical	51	110	0.88 (0.57 - 1.35)	0.548		

Boldface indicates p-values of variables included in multivariate analysis. OR, odds ratio; CI, confidence interval; Ref, reference.
* Mask-wearing adherence was categorized into two groups: good adherence (wearing the mask for ≥ 70% of patient-contact time) and poor adherence (wearing the mask for < 70% of patient-contact time).
[#] Hospitals are categorized into three levels (Level 1, 2 and 3) according to the magnitude: Level 3 > Level 2 > Level 1.
[†] We classified respiratory, emergency and infectious disease wards/departments as being high-risk settings for respiratory pathogen transmission and the surgical one as being low risk.
[‡] It is necessary to wear masks when contacting patients.
** Wash hands after contacting each patient.

Table 4. Predictors of respiratory infection among healthcare workers

Variable	Respiratory infection†		Univariate analysis		Multivariate analysis	
	Yes	No	OR (95% CI)	p-value	OR (95% CI)	p-value
Gender						
Male	37	39	Ref		Ref	
Female	125	199	1.51 (0.91 - 2.50)	**0.106**	2.00 (1.16 - 3.49)	0.013
Age						
< 30	52	76	Ref			
30-40	75	101	0.92 (0.58 - 1.46)	**0.729**		
> 40	35	61	1.19 (0.69 - 2.06)	**0.527**		
Hospital level‡						
Level 2	85	115	Ref		Ref	
Level 3	77	123	1.18 (0.79 - 1.76)	**0.415**	1.72 (1.09 - 2.72)	0.020
Department§						
Low risk	33	47	Ref			
High risk	129	191	1.04 (0.63 - 1.71)	0.879		
Occupation						
Doctor	82	109	Ref			
Nurse	80	129	1.21 (0.81 - 1.81)	**0.344**		
Level of profession						
Senior	83	128	Ref			
Intermediate	55	85	1.48 (0.79 - 2.77)	**0.218**		
Junior	24	25	1.48 (0.77 - 2.86)	**0.238**		
Seasonal influenza vaccination						
No	107	179	Ref		Ref	
Yes	55	59	0.64 (0.41 - 0.99)	**0.046**	0.46 (0.28 - 0.76)	0.002
Frequent hand-washing**						
No	71	130	Ref			
Yes	91	108	0.65 (0.43 - 0.97)	**0.034**		
Patient-contact time						
< 6 h per day	24	31	Ref			
≥ 6 h per day	138	207	1.16 (0.65 - 2.06)	0.610		
Mask type						
Cotton-yarn	89	150	Ref		Ref	
Medical	73	88	0.72 (0.48 - 1.07)	**0.105**	0.60 (0.39 - 0.91)	0.018
Mask-wearing adherence*						
Poor	44	76	Ref		Ref	
Good	118	162	0.80 (0.51 - 1.24)	**0.307**	0.60 (0.37 - 0.98)	0.041

Boldface indicates p-values of variables which were included in multivariate analysis. OR, odds ratio; CI, confidence interval; Ref, reference.

† Defined as having at least two of the following symptoms simultaneously: fever, cough, sore throat, nasal congestion or rhinorrhea.

‡ Hospitals are categorized into three levels (Level 1, 2 and 3) according to the magnitude: Level 3 > Level 2 > Level 1.

§ We classified respiratory, emergency and infectious disease wards/departments as being high-risk settings for respiratory pathogen transmission and the surgical one as being low risk.

** Wash hands after contacting each patient.

* Mask-wearing adherence was categorized into two groups: good adherence (wearing the mask for ≥ 70% of patient-contact time) and poor adherence (wearing the mask for < 70% of patient-contact time).

In this study, female and junior/intermediate HCWs had better adherence to mask-wearing than their counterparts, which may be due to better consciousness of self-protection of females and junior/intermediate HCWs who are much more prone to comply with the hospital infection control policies. HCWs of level 3 hospitals had higher level of adherence to mask-wearing, compared to their counterparts in level 2 facilities. This may be due to the stricter and more complete regulations of infection control in larger hospitals.

HCWs from high risk departments were found to have higher levels of adherence with mask-wearing, compared to their counterparts from low risk areas. This may be due to increased awareness of risk in these departments. We found that it did not matter if the staff member was working in a high or low risk department, anyone who had a "positive attitude" to mask-wearing also had good adherence with mask-wearing. In our study, participants who reported frequent hand-washing were also found to have good adherence with mask-wearing.

In this study close to 60% of participants self-reported having a respiratory infection during the influenza season. Surprisingly, there was no significant difference between rates reported among participants of high risk areas and those from low risk areas. This finding suggested that healthcare workers working in low risk areas had the same risk of respiratory infection as those in high risk areas in Beijing hospitals.

We are unsure why females had a higher reported rate of infection – a possible explanation could be that female healthcare workers have closer patient contact than their male counterparts. The level 3 hospital represented the higher risk of respiratory infection compared to level 2 facilities suggesting that level 3 hospitals, which have larger population of sick patients, are a priority for measures to protect health care workers.

The coverage of seasonal influenza vaccination is always of concern, especially in HCWs.[12-14] In this survey, we found that 28.5% (114/400) of participants were vaccinated, and seasonal influenza vaccination showed a protective effect, underscoring the importance of seasonal influenza vaccination for HCWs.

This study showed that HCWs with good adherence to mask-wearing were at lower risk of respiratory infection, which indicates the protective effect of masks, also found in previous studies.[4-6,15] The protective efficacy of masks/respirators is provided through a combined effect of transmission blocking potential, the fit and related air leakage of the mask/respirator, and the consistency in the use of masks/respirators. Their efficacy is graded on the level of protection the material offers, assuming a perfect fit and optimal compliance.[16] Medical masks are designed to protect the environment from respiratory droplets produced by the wearer. Research studies on the filtration and fit of medical masks show wide variation in penetration of aerosol particles (4% to 90%) and a higher amount of face seal leakage when compared to respirators.[17] The fit of cloth masks/cotton-yarn masks, which are widely used in Asia, is likely to be even looser than medical masks and hence, cloth masks are likely to have a lower level of protection, suggested by the higher efficacy of medical masks found in this study. In addition, reuse of cloth masks may lead to contamination, which adds to the risk of respiratory infection. But there are no clinical data associated with cloth masks currently.

There are a number of limitations in this study. Firstly, information regarding vaccine uptake, frequency of masks/respirators use, frequency of hand washing and cases of respiratory infection were all based on self-report. This study is therefore subject to problems of recall bias, and final results may be overestimated. Another limitation is that we cannot comment on whether HCWs who reported a respiratory infection were infected in or out of the hospital setting.

Despite these limitations, we provide the first quantitative estimate of mask-wearing and respiratory infection among HCWs in Beijing during the influenza season after the SARS outbreak in 2003.

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Exhibit #13

Open Access Research

BMJ Open

A cluster randomised trial of cloth masks compared with medical masks in healthcare workers

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ABSTRACT

Objective: The aim of this study was to compare the efficacy of cloth masks to medical masks in hospital healthcare workers (HCWs). The null hypothesis is that there is no difference between medical masks and cloth masks.

Setting: 14 secondary-level/tertiary-level hospitals in Hanoi, Vietnam.

Participants: 1607 hospital HCWs aged ≥18 years working full-time in selected high-risk wards.

Intervention: Hospital wards were randomised to: medical masks, cloth masks or a control group (usual practice, which included mask wearing). Participants used the mask on every shift for 4 consecutive weeks.

Main outcome measure: Clinical respiratory illness (CRI), influenza-like illness (ILI) and laboratory-confirmed respiratory virus infection.

Results: The rates of all infection outcomes were highest in the cloth mask arm, with the rate of ILI statistically significantly higher in the cloth mask arm (relative risk (RR)=13.00, 95% CI 1.69 to 100.07) compared with the medical mask arm. Cloth masks also had significantly higher rates of ILI compared with the control arm. An analysis by mask use showed ILI (RR=6.64, 95% CI 1.45 to 28.65) and laboratory-confirmed virus (RR=1.72, 95% CI 1.01 to 2.94) were significantly higher in the cloth masks group compared with the medical masks group. Penetration of cloth masks by particles was almost 97% and medical masks 44%.

Conclusions: This study is the first RCT of cloth masks, and the results caution against the use of cloth masks. This is an important finding to inform occupational health and safety. Moisture retention, reuse of cloth masks and poor filtration may result in increased risk of infection. Further research is needed to inform the widespread use of cloth masks globally. However, as a precautionary measure, cloth masks should not be recommended for HCWs, particularly in high-risk situations, and guidelines need to be updated.

Trial registration number: Australian New Zealand Clinical Trials Registry: ACTRN12610000887077.

Strengths and limitations of this study

- The use of cloth masks is widespread around the world, particularly in countries at high-risk for emerging infections, but there have been no efficacy studies to underpin their use.
- This study is large, a prospective randomised clinical trial (RCT) and the first RCT ever conducted of cloth masks.
- The use of cloth masks are not addressed in most guidelines for health care workers—this study provides data to update guidelines.
- The control arm was 'standard practice', which comprised mask use in a high proportion of participants. As such (without a no-mask control), the finding of a much higher rate of infection in the cloth mask arm could be interpreted as harm caused by cloth masks, efficacy of medical masks, or most likely a combination of both.

INTRODUCTION

The use of facemasks and respirators for the protection of healthcare workers (HCWs) has received renewed interest following the 2009 influenza pandemic,[1] and emerging infectious diseases such as avian influenza,[2] Middle East respiratory syndrome coronavirus (MERS-coronavirus)[3 4] and Ebola virus.[5] Historically, various types of cloth/cotton masks (referred to here after as 'cloth masks') have been used to protect HCWs.[6] Disposable medical/surgical masks (referred to here after as 'medical masks') were introduced into healthcare in the mid 19th century, followed later by respirators.[7] Compared with other parts of the world, the use of face masks is more prevalent in Asian countries, such as China and Vietnam.[8–11]

In high resource settings, disposable medical masks and respirators have long since replaced the use of cloth masks in hospitals. Yet cloth masks remain widely used

globally, including in Asian countries, which have historically been affected by emerging infectious diseases, as well as in West Africa, in the context of shortages of personal protective equipment (PPE).[12 13] It has been shown that medical research disproportionately favours diseases of wealthy countries, and there is a lack of research on the health needs of poorer countries.[11] Further, there is a lack of high-quality studies around the use of facemasks and respirators in the healthcare setting, with only four randomised clinical trials (RCTs) to date.[15] Despite widespread use, cloth masks are rarely mentioned in policy documents,[16] and have never been tested for efficacy in a RCT. Very few studies have been conducted around the clinical effectiveness of cloth masks, and most available studies are observational or in vitro.[6] Emerging infectious diseases are not constrained within geographical borders, so it is important for global disease control that use of cloth masks be underpinned by evidence. The aim of this study was to determine the efficacy of cloth masks compared with medical masks in HCWs working in high-risk hospital wards, against the prevention of respiratory infections.

METHODS

A cluster-randomised trial of medical and cloth mask use for HCWs was conducted in 14 hospitals in Hanoi, Vietnam. The trial started on the 3 March 2011, with rolling recruitment undertaken between 3 March 2011 and 10 March 2011. Participants were followed during the same calendar time for 4 weeks of facemasks use and then one additional week for appearance of symptoms. An invitation letter was sent to 32 hospitals in Hanoi, of which 16 agreed to participate. One hospital did not meet the eligibility criteria; therefore, 74 wards in 15 hospitals were randomised. Following the randomisation process, one hospital withdrew from the study because of a nosocomial outbreak of rubella.

Participants provided written informed consent prior to initiation of the trial.

Randomisation

Seventy-four wards (emergency, infectious/respiratory disease, intensive care and paediatrics) were selected as high-risk settings for occupational exposure to respiratory infections. Cluster randomisation was used because the outcome of interest was respiratory infectious diseases, where prevention of one infection in an individual can prevent a chain of subsequent transmission in closed settings.[8 9] Epi info V.6 was used to generate a randomisation allocation and 74 wards were randomly allocated to the interventions.

From the eligible wards 1868 HCWs were approached to participate. After providing informed consent, 1607 participants were randomised by ward to three arms: (1) medical masks at all times on their work shift; (2) cloth masks at all times on shift or (3) control arm (standard practice, which may or may not include mask use). Standard practice was used as control because the IRB deemed it unethical to ask participants to not wear a mask. We studied continuous mask use (defined as wearing masks all the time during a work shift, except while in the toilet or during tea or lunch breaks) because this reflects current practice in high-risk settings in Asia.[8]

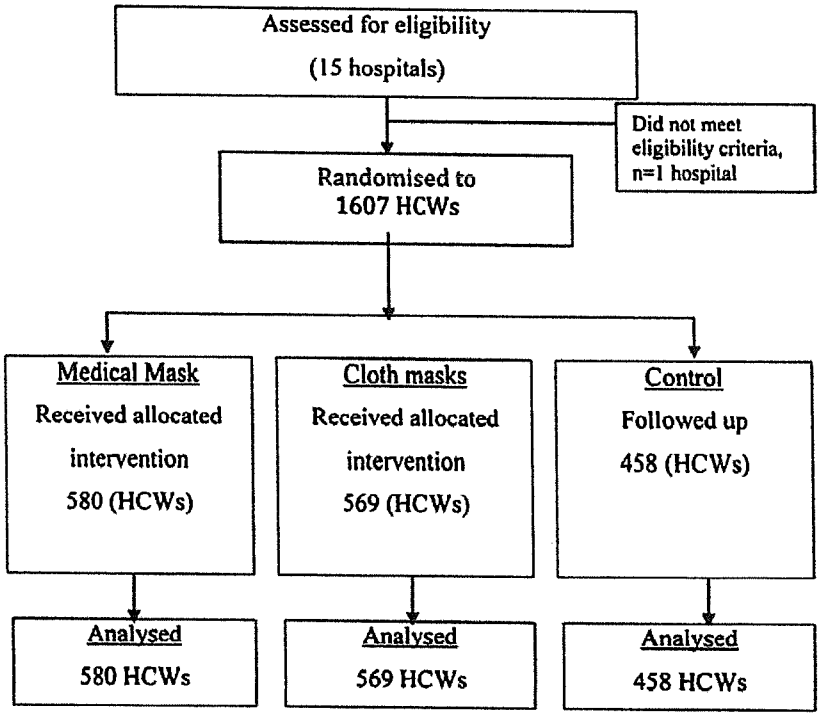

Figure 1 Consort diagram of recruitment and follow-up (HCWs, healthcare workers).

The laboratory results were blinded and laboratory testing was conducted in a blinded fashion. As facemask use is a visible intervention, clinical end points could not be blinded. Figure 1 outlines the recruitment and randomisation process.

Primary end points

There were three primary end points for this study, used in our previous mask RCTs:[8 9] (1) Clinical respiratory illness (CRI), defined as two or more respiratory symptoms or one respiratory symptom and a systemic symptom;[17] (2) influenza-like illness (ILI), defined as fever ≥38°C plus one respiratory symptom and (3) laboratory-confirmed viral respiratory infection. Laboratory confirmation was by nucleic acid detection using multiplex reverse transcriptase PCR (RT-PCR) for 17 respiratory viruses: respiratory syncytial virus (RSV) A and B, human metapneumovirus (hMPV), influenza A (H3N2), (H1N1)pdm09, influenza B, parainfluenza viruses 1–4, influenza C, rhinoviruses, severe acute respiratory syndrome (SARS) associated coronavirus (SARS-CoV), coronaviruses 229E, NL63, OC43 and HKU1, adenoviruses and human bocavirus (hBoV).[18–23] Additional end points included compliance with mask use, defined as using the mask during the shift for 70% or more of work shift hours.[9] HCWs were categorised as 'compliant' if the average use was equal or more than 70% of the working time. HCW were categorised as 'non-compliant' if the average mask use was less than 70% of the working time.

Eligibility

Nurses or doctors aged ≥18 years working full-time were eligible. Exclusion criteria were: (1) Unable or refused to consent; (2) Beards, long moustaches or long facial hair stubble; (3) Current respiratory illness, rhinitis and/or allergy.

Intervention

Participants wore the mask on every shift for four consecutive weeks. Participants in the medical mask arm were supplied with two masks daily for each 8 h shift, while participants in the cloth mask arm were provided with five masks in total for the study duration, which they were asked to wash and rotate over the study period. They were asked to wash cloth masks with soap and water every day after finishing the shifts. Participants were supplied with written instructions on how to clean their cloth masks. Masks used in the study were locally manufactured medical (three layer, made of non-woven material) or cloth masks (two layer, made of cotton) commonly used in Vietnamese hospitals. The control group was asked to continue with their normal practices, which may or may not have included mask wearing. Mask wearing was measured and documented for all participants, including the control arm.

Data collection and follow-up

Data on sociodemographic, clinical and other potential confounding factors were collected at baseline. Participants were followed up daily for 4 weeks (active intervention period), and for an extra week of standard practice, in order to document incident infection after incubation. Participants received a thermometer (traditional glass and mercury) to measure their temperature daily and at symptom onset. Daily diary cards were provided to record number of hours worked and mask use, estimated number of patient contacts (with/without ILI) and number/type of aerosol-generating procedures (AGPs) conducted, such as suctioning of airways, sputum induction, endotracheal intubation and bronchoscopy. Participants in the cloth mask and control group (if they used cloth masks) were also asked to document the process used to clean their mask after use.

We also monitored compliance with mask use by a previously validated self-reporting mechanism.[8] Participants were contacted daily to identify incident cases of respiratory infection. If participants were symptomatic, swabs of both tonsils and the posterior pharyngeal wall were collected on the day of reporting.

Sample collection and laboratory testing

Trained collectors used double rayon-tipped, plastic-shafted swabs to scratch tonsillar areas as well as the posterior pharyngeal wall of symptomatic participants. Testing was conducted using RT-PCR applying published methods.[19–23] Viral RNA was extracted from each respiratory specimen using the Viral RNA Mini kit (Qiagen, Germany), following the manufacturer's instructions. The RNA extraction step was controlled by amplification of a RNA house-keeping gene (amplify pGEM) using real-time RT-PCR. Only extracted samples with the house keeping gene detected by real-time RT-PCR were submitted for multiplex RT-PCR for viruses.

The reverse transcription and PCRs were performed in OneStep (Qiagen, Germany) to amplify viral target genes, and then in five multiplex RT-PCR: RSVA/B, influenza A/H3N2, A(H1N1) and B viruses, hMPV (reaction mix 1); parainfluenza viruses 1–4 (reaction mix 2); rhinoviruses, influenza C virus, SARS-CoV (reaction mix 3); coronaviruses OC43, 229E, NL63 and HKU1 (reaction mix 4); and adenoviruses and hBoV (reaction mix 5), using a method published by others.[18] All samples with viruses detected by multiplex RT-PCR were confirmed by virus-specific mono nested or hemi-nested PCR. Positive controls were prepared by in vitro transcription to control amplification efficacy and monitor for false negatives, and included in all runs (except for NL63 and HKU1). Each run always included two negatives to monitor amplification quality. Specimen processing, RNA extraction, PCR amplification and PCR product analyses were conducted in different rooms to avoid cross-contamination.[19 20]

Filtration testing

The filtration performance of the cloth and medical masks was tested according to the respiratory standard AS/NZS1716.[24] The equipment used was a TSI 8110 Filter tester. To test the filtration performance, the filter is challenged by a known concentration of sodium chloride particles of a specified size range and at a defined flow rate. The particle concentration is measured before and after adding the filter material and the relative filtration efficiency is calculated. We examined the performance of cloth masks compared with the performance levels—P1, P2 (=N95) and P3, as used for assessment of all particulate filters for respiratory protection. The 3M 9320 N95 and 3M Vflex 9105 N95 were used to compare against the cloth and medical masks.

Sample size calculation

To obtain 80% power at two-sided 5% significance level for detecting a significant difference of attack rate between medical masks and cloth masks, and for a rate of infection of 13% for cloth mask wearers compared with 6% in medical mask wearers, we would need eight clusters per arm and 530 participants in each arm, and intracluster correlation coefficient (ICC) 0.027, obtained from our previous study.[8] The design effect (deff) for this cluster randomisation trial was 1.65 (deff=1+(m −1)×ICC=1+(25−1)×0.027=1.65). As such, we aimed to recruit a sample size of 1600 participants from up to 15 hospitals.

Analysis

Descriptive statistics were compared among intervention and control arms. Primary end points were analysed by intention to treat. We compared the event rates for the primary outcomes across study arms and calculated p values from cluster-adjusted χ^2 tests[25] and ICC.[25 26] We also estimated relative risk (RR) after adjusting for clustering using a log-binomial model under generalised estimating equation (GEE) framework.[27] We checked for variables which were unequally distributed across arms, and conducted an adjusted analysis accordingly. We fitted a multivariable log-binomial model using GEE to account for clustering by ward, to estimate RR after adjusting for potential confounders. In the initial model, we included all the variables that had p value less than 0.25 in the univariable analysis, along with the main exposure variable (randomisation arm). A backward elimination method was used to remove the variables that did not have any confounding effect.

As most participants in the control arm used a mask during the trial period, we carried out a post-hoc analysis comparing all participants who used only a medical mask (from the control arm and the medical mask arm) with all participants who used only a cloth mask (from the control arm and the cloth arm). For this analysis, controls who used both types of mask (n=245) or used N95 respirators (n=3) or did not use any masks (n=2) were excluded. We fitted a multivariable log-binomial model, to estimate RR after adjusting for potential confounders. As we pooled data of participants from all three arms and analysed by mask type, not trial arm, we did not adjust for clustering here. All statistical analyses were conducted using STATA V.12.[28]

Owing to a very high level of mask use in the control arm, we were unable to determine whether the differences between the medical and cloth mask arms were due to a protective effect of medical masks or a detrimental effect of cloth masks. To assist in interpreting the data, we compared rates of infection in the medical mask arm with rates observed in medical mask arms from two previous RCTs,[8 9] in which no efficacy of medical masks could be demonstrated when compared with control or N95 respirators, recognising that seasonal and geographic variation in virus activity affects the rates of exposure (and hence rates of infection outcomes) among HCWs. This analysis was possible because the trial designs were similar and the same outcomes were measured in all three trials. The analysis was carried out to determine if the observed results were explained by a detrimental effect of cloth masks or a protective effect of medical masks.

RESULTS

A total of 1607 HCWs were recruited into the study. The participation rate was 86% (1607/1868). The average number of participants per ward was 23 and the mean age was 36 years. On average, HCWs were in contact with 36 patients per day during the trial period (range 0–661 patients per day, median 20 patients per day). The distribution of demographic variables was generally similar between arms (table 1). Figure 2 shows the primary outcomes for each of the trial arms. The rates of CRI, ILI and laboratory-confirmed virus infections were lowest in the medical mask arm, followed by the control arm, and highest in the cloth mask arm.

Table 2 shows the intention-to-treat analysis. The rate of CRI was highest in the cloth mask arm, followed by the control arm, and lowest in the medical mask arm. The same trend was seen for ILI and laboratory tests confirmed viral infections. In intention-to-treat analysis, ILI was significantly higher among HCWs in the cloth masks group (RR=13.25 and 95% CI 1.74 to 100.97), compared with the medical masks group. The rate of ILI was also significantly higher in the cloth masks arm (RR=3.49 and 95% CI 1.00 to 12.17), compared with the control arm. Other outcomes were not statistically significant between the three arms.

Among the 68 laboratory-confirmed cases, 58 (85%) were due to rhinoviruses. Other viruses detected were hMPV (7 cases), influenza B (1 case), hMPV/rhinovirus co-infection (1 case) and influenza B/rhinovirus co-infection (1 case) (table 3). No influenza A or RSV infections were detected.

Compliance was significantly higher in the cloth mask arm (RR=2.41, 95% CI 2.01 to 2.88) and medical masks

Table 1 Demographic and other characteristics by arm of randomisation

Variable	Medical mask (% and 95% CI) (n=580)	Cloth mask (% and 95% CI) (n=569)	Control (% and 95% CI) (n=458)
Gender (male)	112/580	133/569	112/458
	19.3 (16.2 to 22.8)	23.4 (20.0 to 27.1)	24.5 (20.6 to 28.7)
Age (mean)	36 (35.6 to 37.3)	35 (34.6 to 36.3)	36 (35.1 to 37.0)
Education (postgraduate)	114/580	99/569	78/458
	19.7 (16.5 to 23.1)	17.4 (14.3 to 20.8)	17.0 (13.7 to 20.8)
Smoker (current/ex)	78/580	79/569	66/458
	13.4 (10.8 to 16.5)	13.9 (11.1 to 17.0)	14.4 (11.3 to 18.0)
Pre-existing illness*	66/580	70/569	47/458
	11.4 (9.0 to 14.2)	12.3 (9.8 to 15.3)	10.3 (7.8 to 13.4)
Influenza vaccination (yes)	21/580	21/569	15/458
	3.6 (2.4 to 5.4)	3.7 (2.4 to 5.6)	3.3 (2.0 to 5.3)
Staff (doctors)	176/580	165/569	134/458
	30.3 (26.6 to 34.3)	29.0 (25.3 to 32.9)	29.3 (25.1 to 33.7)
Number of hand washings per day (geometric mean)†	14 (13.8 to 15.4)	11 (10.9 to 11.9)	12 (11.5 to 12.7)
Number of patients had contact with (median and range)‡	21 (0 to 540)	21 (0 to 661)	18 (3 to 199)

*Includes asthma, immunocompromised and others.
†'Hand wash' variable was created by taking average of the number of hand washes performed by a healthcare worker (HCW) over the trial period. The variable was log transformed for the multivariate analysis.
‡'Number of patients had contact with' variable was created by taking average of the number of patients in contact with a HCW over the trial period. Median and range is presented in the table.

arm (RR=2.40, 95% CI 2.00 to 2.87), compared with the control arm. Figure 3 shows the percentage of participants who were compliant in the three arms. A post-hoc analysis adjusted for compliance and other potential confounders showed that the rate of ILI was significantly higher in the cloth mask arm (RR=13.00, 95% CI 1.69 to 100.07), compared with the medical masks arm (table 4). There was no significant difference between the medical mask and control arms. Hand washing was significantly protective against laboratory-confirmed viral infection (RR=0.66, 95% CI 0.44 to 0.97).

In the control arm, 170/458 (37%) used medical masks, 38/458 (8%) used cloth masks, and 245/458 (53%) used a combination of both medical and cloth masks during the study period. The remaining 1% either reported using a N95 respirator (n=3) or did not use any masks (n=2).

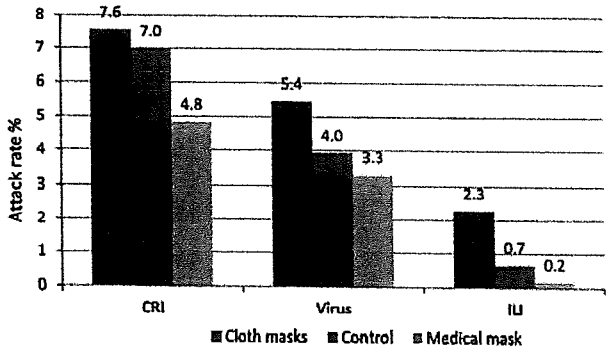

Figure 2 Outcomes in trial arms (CRI, clinical respiratory illness; ILI, influenza-like illness; Virus, laboratory-confirmed viruses).

Table 5 shows an additional analysis comparing all participants who used only a medical mask (from the control arm and the medical mask arm) with all participants who used only a cloth mask (from the control arm and the cloth arm). In the univariate analysis, all outcomes were significantly higher in the cloth mask group, compared with the medical masks group. After adjusting for other factors, ILI (RR=6.64, 95% CI 1.45 to 28.65) and laboratory-confirmed virus (RR=1.72, 95% CI 1.01 to 2.94) remained significantly higher in the cloth masks group compared with the medical masks group.

Table 6 compares the outcomes in the medical mask arm with two previously published trials.[8 9] This shows that while the rates of CRI were significantly higher in one of the previously published trials, the rates of laboratory-confirmed viruses were not significantly different between the three trials for medical mask use.

On average, HCWs worked for 25 days during the trial period and washed their cloth masks for 23/25 (92%) days. The most common approach to washing cloth masks was self-washing (456/569, 80%), followed by combined self-washing and hospital laundry (91/569, 16%), and only hospital laundry (22/569, 4%). Adverse events associated with facemask use were reported in 40.4% (227/562) of HCWs in the medical mask arm and 42.6% (242/568) in the cloth mask arm (p value 0.450). General discomfort (35.1%, 397/1130) and breathing problems (18.3%, 207/1130) were the most frequently reported adverse events.

Table 5 Univariate and adjusted analysis comparing participants who used medical masks and cloth masks*

	Univariate RR (95% CI)	Adjusted RR (95% CI)
CRI		
Medical mask (35/750, 4.67%)	Ref	Ref
Cloth mask (46/607, 7.58%)	**1.62 (1.06 to 2.49)**	1.51 (0.97 to 2.32)
Male	0.60 (0.32 to 1.12)	0.58 (0.31 to 1.08)
Vaccination	0.66 (0.17 to 2.62)	0.68 (0.17 to 2.67)
Hand washing	0.81 (0.58 to 1.15)	0.84 (0.59 to 1.20)
Compliance	1.01 (1.00 to 1.03)	1.01 (1.00 to 1.02)
ILI		
Medical mask (2/750, 0.27%)	Ref	Ref
Cloth mask (13/607, 2.14%)	**8.03 (1.82 to 35.45)**	**6.64 (1.45 to 28.65)**
Male	0.95 (0.27 to 3.35)	0.92 (0.26 to 3.22)
Vaccination	1.87 (0.25 to 13.92)	1.97 (0.27 to 14.45)
Hand washing	0.56 (0.24 to 1.27)	0.61 (0.23 to 1.57)
Compliance	1.04 (1.01 to 1.08)	1.04 (1.00 to 1.08)
Laboratory-confirmed viruses		
Medical mask (22/750, 2.93%)	Ref	Ref
Cloth mask (34/607, 5.60%)	**1.91 (1.13 to 3.23)**	**1.72 (1.01 to 2.94)**
Male	0.64 (0.30 to 1.33)	0.61 (0.29 to 1.27)
Vaccination	0.97 (0.24 to 3.86)	1.03 (0.26 to 4.08)
Hand washing	0.61 (0.41 to 0.93)	0.65 (0.42 to 1.00)
Compliance	1.00 (0.99 to 1.02)	1.0 (0.99 to 1.02)

Bold typeface indicates statistically significant.
*The majority (456/458) of HCWs in the control arm used a mask. Controls who exclusively used a medical mask were categorised and analysed with the medical mask arm participants; and controls who exclusively wore a cloth mask were categorised and analysed with the cloth mask arm.
CRI, clinical respiratory illness; HCWs, healthcare workers; ILI, influenza-like illness; RR, relative risk.

Table 6 A comparison of outcome data for the medical mask arm with medical mask outcomes in previously published RCTs

	CRI N (%)	RR (95% CI)	ILI N (%)	RR (95% CI)	Laboratory-confirmed viruses N (%)	RR (95% CI)
Vietnam trial	28/580 (4.83)	Ref	1/580 (0.17)	Ref	19/580 (3.28)	Ref
Published RCT China 1[8]	33/492 (6.70)	1.40 (0.85 to 2.26)	3/492 (0.61)	3.53 (0.37 to 33.89)	13/492 (2.64)	0.80 (0.40 to 1.62)
Published RCT China 2[9]	98/572 (17.13)	**3.54 (2.37 to 5.31)**	4/572 (0.70)	4.06 (0.45 to 36.18)	19/572 (3.32)	1.01 (0.54 to 1.89)

Bold typeface indicates statistically significant.
CRI, Clinical respiratory illness; ILI, influenza-like illness; RCT, randomised clinical trial; RR, relative risk.

Pandemics and emerging infections are more likely to arise in low-income or middle-income settings than in wealthy countries. In the interests of global public health, adequate attention should be paid to cloth mask use in such settings. The data from this study provide some reassurance about medical masks, and are the first data to show potential clinical efficacy of medical masks. Medical masks are used to provide protection against droplet spread, splash and spray of blood and body fluids. Medical masks or respirators are recommended by different organisations to prevent transmission of Ebola virus, yet shortages of PPE may result in HCWs being forced to use cloth masks.[3 5–10] In the interest of providing safe, low-cost options in low income countries, there is scope for research into more effectively designed cloth masks, but until such research is carried out, cloth masks should not be recommended. We also recommend that infection control guidelines be updated about cloth mask use to protect the occupational health and safety of HCWs.

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grant; however they were not involved in study design, data collection or analysis. The 3M products were not used in this study.

Contributors CRM was the lead investigator, and responsible for the conception and design of the trial, obtaining the grant funding, overseeing the whole study, analysing the data and writing of the report. HS contributed to overseeing the study, staff training, form/database development and drafting of the manuscript. TCD was responsible for overseeing the study, database management, recruitment, training and revision of the manuscript. NTH was responsible for the implementation of research and revision of the manuscript. PTN was responsible for the laboratory testing in Vietnam. AAC contributed to the statistical analysis and drafting of the manuscript. BR was responsible for the statistical analysis and revision of the manuscript. DED contributed to the laboratory technical assistance and revision of the manuscript. QW assisted in comparing the rates of infection from two previous RCTs conducted in China and revision of the manuscript.

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Competing interests CRM has held an Australian Research Council Linkage Grant with 3M as the industry partner, for investigator-driven research. 3M has also contributed masks and respirators for investigator-driven clinical trials. CRM has received research grants and laboratory testing as in-kind support from Pfizer, GSK and Bio-CSL for investigator-driven research. HS had a NHMRC Australian-based Public Health Training Fellowship at the time of the study (1012631). She has also received funding from vaccine manufacturers GSK, bio-CSL and Sanofi Pasteur for investigator-driven research and presentations. AAC used filtration testing of masks for his PhD thesis conducted by 3M Australia.

Ethics approval National Institute for Hygiene and Epidemiology (NIHE) (approval number 05 IRB) and the Human Research Ethics Committee of the University of New South Wales (UNSW), Australia, (HREC approval number 10306).

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Exhibit #14

National Academies Press

Rapid Expert Consultation on the Effectiveness of Fabric Masks for the COVID-19 Pandemic (April 8, 2020)

April 8, 2020 Kelvin Droegemeier, Ph.D. Ofxce of Science and Technology Policy Executive Ofxce of the President Eisenhower Executive Office Building 1650 Pcnnsylvania Avenue, NW Washington, DC 20504 Dear Dr. Droegemeier: Attached please find a rapid expert consultation that was prepared by Rich Besser and Baruch Fischhoff, members of the National Academies of Sciences, Engineering, and Medicine's Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats, with input from Sundaresan Jayaraman and Michael Osterholm.

Details on the authors and reviewers of this rapid expert consultation can be found in the Appendix.

The aim of this rapid expert consultation is to respond to your request concerning the effectiveness of homemade fabric masks worn by the general public to protect others, as distinct from protecting the wearer. The request stems from an interest in reducing transmission within the community by individuals who are infected, potentially contagious, but asymptomatic. Overall, the available evidence is inconclusive about the degree to which homemade fabric masks may suppress the spread of infection from the wearer to others. For as long as homemade fabric masks are in use by the public, the investigations outlined at the end of the rapid expert consultation could reduce uncertainty about the effectiveness of these masks.

My colleagues and I hope this input is helpful to you as you continue to guide the nation's response in this ongoing public health crisis.

Respectfully, Harvey V. Fineberg, M.D., Ph.D. Chair Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

This rapid expert consultation responds to your request concerning the effectiveness of homemade fabric masks worn by the general public to protect others, as distinct from protecting the wearer. The request stems from an interest in reducing transmission within the community by individuals who are infected, potentially contagious, but asymptomatic or presymptomatic. As discussed below, the answer depends on both the masks themselves and how infected individuals use them.

The following analysis is restricted to the effectiveness of homemade fabric masks, of the sort illustrated in recommendations1 directed at the general public, in terms of their ability to reduce viral spread during the asymptomatic or presymptomatic period. It does not apply to either N95respirators or medical masks.

In considering the evidence about the potential effectiveness of homemade fabric masks, it is important to bear in mind how a respiratory virus such as SARS-CoV-2 spreads from person to person. Current research supports the possibility that, in addition to being spread by respiratory

droplets that one can see and feel, SARS-CoV-2 can also be spread by invisible droplets, as small as 5 microns (or micrometers), and by even smaller bioaerosolparticles.2 Such tiny bioaerosol particles may be found in an infected person's normal exhalation.3 The relative contribution of each particle size in disease transmission is unknown.

There is limited research on the efficacy of fabric masks for influenza and specifically for SARSCoV-2. As we describe below, the few available experimental studies have important limitations in their relevance and methods. Any type of mask will have its own capacity to arrest particles of different sizes. Even if the filtering capacity of a mask were well understood, however, the degree to which it could in practice reduce disease spread depends on the unknown role of each particle size in transmission.

Asymptomatic but infected individuals are of special concern, and the particles they would emit from breathing are predominantly bioaerosols. To complicate matters further, different individuals vary in the extent to which they emit bioaerosols while breathing. Because of the concern with spread from asymptomatic individuals, who, unlike symptomatic persons, may be out and about, this rapid expert consultation includes the effects of fabric masks on bioaerosol transmission.

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1 Centers for Disease Control and Prevention (CDC) Recommendation Regarding the Use of Cloth Face Coverings, Especially in Areas of Significant Community-Based Transmission in response to COVID-19. https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover.html. 2 Gralton et al. (2011) noted the following in regard to particulate size and the importance of airborne precautions whenever there is a risk of both droplet and aerosol transmission: "Regardless of the complexities and limitations of sizing particles and the contention of size cut-offs, it remains that particles have been observed to occupy a size range between 0.05 and 500 microns. Even using the conservative cut-off of 10 microns, rather than the 5 micron to define between airborne and droplet transmission, this size range indicates that particles do not exclusively disperse by airborne transmission or via droplet transmission but rather avail of both methods simultaneously. This suggestion is further supported by the simultaneous detection of both large and small particles. In line with these observations and logic, current dichotomous infection control precautions should be updated to include measures to contain both modes of aerosolised transmission. This may require airborne precautions to be used when at risk of any aerosolized infection, as airborne precautions are considered as a step-up from droplet precautions." Gralton et al. 2011. The role of particle size in aerosolised pathogen transmission: A review. Journal of Infection 62(1).1-13. DOI: 10.1016/j.jinf.2010.11.010. 3 National Academies of Sciences, Engineering, and Medicine. 2020. Rapid Expert Consultation on the Possibility of Bioaerosol Spread of SARS-CoV-2 for the COVID-19Pandemic (April 1, 2020). Washington, DC: The National Academies Press. https://doi.org/10.17226/25769.

IMPACT OF MASK DESIGN AND FABRICATION ON PERFORMANCE

Any effects of fabric masks will depend on how and how well they are made. In an unpublished study whose raw data are not currently available, Jayaraman et al.4 examined a range of fabric-based filtration systems, in terms of how well they stopped particles (filtration efficiency) and how much they impeded breathing (differential pressure, Delta-P, the measured pressure drop across the material, which determines the resistance of the material to air yow).5 The study varied fabric type (woven, woven brushed, knitted, knitted brushed, knitted pile), material type (cotton, polyester, polypropylene, silk), fabric parameters (fabric areal density, yarn linear density, fabric weight), and construction type (number of layers, orientation of the layers). The study found wide variation in filtration efficiency. A mask made from a four-layer woven handkerchief fabric, of a sort that might be found in many homes, had 0.7% filtration efficiency for0.3 micron size particles and a Delta-P of 0.1". Much higher filtration efficiency was observed with filters created specifically for the research from a five-layer woven brushed fabric (35.3% of the particles were trapped) and from four layers of polyester knitted cut-pile fabric (50% of the particles were trapped with a Delta-P of 0.2").

The greater a mask's breathing resistance, which is reflected in a higher Delta-P, the more difficult it is for users to wear it consistently, and the more likely they are to experience breathing difficulties when they do.6Although Jayaraman et al. did not measure breathing resistance directly, almost all of the masks they tested would be expected to have breathing resistance within the range of commercial N95 respirators. One mask that used 16 layers of the handkerchief fabric, in order to increase filtration efficiency (63% efficiency with a Delta-P of 0.425"), had breathing resistance greater than that of commercial N95 respirators, which would cause great discomfort to many wearers and cause some to pass out.

An additional consideration in the effectiveness of any mask is how well it fits the user.7 Even with the best material, if a mask does not fit, virus-containing particles can escape through creases and gaps between the mask and face. Leakage can also occur if the holding mechanism (e.g., straps, Velcro®) is weak. We found no studies of non-expert individuals' ability to produce properly fitting masks. Nor did we find any studies of the effectiveness of masks produced by professionals, when following instructions available to the general public (e.g., online). Given the current Centers for Disease Control and Prevention (CDC) recommendation to wear cloth face coverings in public settings in areas of significant community-based transmission, additional research should examine the ability of the general public to produce properly fitted fabric masks when following communications and instructions.

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4 Jayaraman et al. Pandemic Flu—Textile Solutions Pilot: Design and Development of Innovative Medical Masks, Final Technical Report, Georgia Institute of Technology, Atlanta, Georgia, submitted to CDC, February 14, 2012. 5 The tests were conducted according to ASTM F2299-3 test method using poly-dispersed sodium chloride aerosol particles with an air yow rate of 30L/min and airflow velocity of 11 cm/s. Aerosol sizes measured: 0.1, 0.2, 0.3, 0.4, 0.5, 0.7, 1, and 2microns. 6 3M™ Health Care Particulate Respirator and Surgical Masks, Healthcare Respirator Brochure, 3M Company, Minnesota. 7 Davies et al. (2013) noted that, "Although any material may provide a physical barrier to an infection, if as a mask it does not fit well around the nose and mouth, or the

material freely allows infectious aerosols to pass through it, then it will be of no be next." Davies et al. 2013. Testing the efficacy of homemade masks: Would they protect in an influenza pandemic? Disaster Medicine and Public Health Preparedness7(4).413-418. DOI: 10.1017/dmp.2013.43.

ROLE OF THE WEARER

The effectiveness of homemade fabric masks will also depend on the wearer's behavior. Even if a mask could fit well, its effectiveness still depends on how well the wearer puts it on and keeps it in place. As mentioned, breathing difficulty can impede effective use (e.g., pulling a mask down), as can moisture from the wearer's breath. Moisture saturation is inevitable with fabrics available in most homes. Moreover, moisture can trap the virus and become a potential contamination source for others after a mask is removed.

EFFECTIVENESS OF HOMEMADE FABRICMASKS IN PROTECTING OTHERS

Several experimental studies have examined the effects of fabric masks on the transmission of droplets of various sizes.

Anfinrud et al.[8] shared via email that they used sensitive laser light-scattering procedures to detect droplet emission while people were speaking. The authors found that "a damp homemade cloth facemask" reduced droplet emission to background levels (when users said "Stay Healthy" three times). However, when a fabric is dampened, the yarns can swell over time, potentially altering its filtering performance. That swelling will depend on the fabric: cotton swells readily, synthetics less so. In an unpublished follow-up experiment, Anfinrud et al. repeated their study with a variety of dry (not moistened) cloths, including a standard workers dust mask (not certified N95) and a mask rigged from an airline eye covering. They found that all of these masks reduced droplet emission generated by speech to background level.9

Bae et al. (2020) evaluated the effectiveness of surgical and cotton masks in filtering SARSCoV-2.10 They found that neither kind of mask reduced the dissemination of SARS-CoV-2 from the coughs of four symptomatic patients with COVID-19 to the environment and external mask surface. The study used disposable surgical masks (180 mm × 90 mm, 3 layers [inner surface mixed with polypropylene and polyethylene, polypropylene filter, and polypropylene outer surface], pleated, bulk packaged in cardboard; KM Dental Mask, KM Healthcare Corp) and reusable 100% cotton masks (160mm × 135 mm, 2 layers, individually packaged in plastic; Seoulsa). The median viral loads of nasopharyngeal and saliva samples from the four participants were 5.66 log copies/mL and 4.00 log copies/mL, respectively. The median viral loads after coughs without a mask, with a surgical mask, and with a cotton mask were similar: 2.56 log copies/mL, 2.42 log copies/mL, and 1.85 log copies/mL, respectively. All swabs from the outer mask surfaces of the masks were positive for SARS-CoV-2, whereas swabs from three out of the four symptomatic patients from the inner mask surfaces were negative. Note that this study focused on symptomatic patients who coughed.

8 Anfinrud et al. In Press. Could SARS-CoV-2 be transmitted via speech droplets? New England Journal of Medicine. https://doi.org/10.1101/2020.04.02.20051177.

9 Personal communication, Adriaan Bax, National Institutes of Health, April 4, 2020.

10 Bae et al. 2020. Effectiveness of surgical and cotton masks in blocking SARS-CoV-2. A controlled comparison in 4 patients. Annals of Internal Medicine. DOI:10.7326/M20-1342.

Rengasamy et al. (2010)11 tested the filtration performance of five common household fabric materials: sweatshirts, T-shirts, towels, scarves, and cloth masks (of unknown material) in a laboratory setting. These fabric materials were tested for sprays having both similar and diverse particle sizes(monodisperse and polydisperse). The range of sizes used in the study(0.02-1 micron) includes that of potential virus-containing droplets.12 The study projected the particles at face velocities, typical of breathing at rest and during exertion (5.5 and 16.5 cm/s). The test also examined N95respirator filter media. At the lower velocity, 0.12% of particles penetrated the N95 respirator material; at the higher velocity, penetration was less than 5%. For the five common household fabric materials, across the tests, penetration ranged from about 40-90%, indicating a 10-60% reduction. The authors concluded that common fabric materials may provide a low level of protection against nanoparticles, including those in the size ranges of virus-containing particles in exhaled breath (0.02-1 micron). However, Gralton et al. (2011) found particles generated from respiratory activities range from 0.01 up to 500 microns, with a particle size range of 0.05 to 500microns associated with infection. They stress the need for airborne precautions to be used when at risk of any aerosolized infection, as airborne precautions are considered as a step-up from droplet precautions.

Davies et al. (2013)13 had 21 healthy volunteers make their own face masks from fresh, unworn cotton t-shirts. This is the only study we found with user-made masks. Participants then coughed into a box, when wearing their own mask, a surgical mask, or no mask. They received no help or guidance from the researcher in making or fitting their masks. The researchers took samples of particles settling onto agar plates and a Casella slit sampler in the box. Under the baseline conditions of no mask, only a small number of colony-forming units (indicative of bacteria) were detected, limiting the opportunity to demonstrate reductions. Still, the investigators reported that both homemade and surgical masks reduced the number of large-sized microorganisms expelled by volunteers, with the surgical mask being more effective.

van der Sande et al. (2008)14 examined the extent to which respirator masks, surgical masks, and tea-cloth masks made by the researchers would reduce tiny (0.02-1 micron) particle counts on one side of the mask compared to the other. They used burning candles in a test room to generate particles. Two of the study's three experiments examined the protection afforded the wearer (reduced particle counts inside the masks compared to outside). Although not directly germane to the question of protecting others, the study found a modest degree of protection for the wearer from cloth masks, an intermediate degree from surgical masks, and a marked degree with the equivalent of N95 masks. For example, among adults, N95 masks provided 25 times the protection of surgical masks and50 times the protection of cloth masks. The study's third

11 Rengasamy et al. 2010. Simple respiratory protection—evaluation of the filtration performance of cloth masks and common fabric materials against 20-1000 nm size particles. Annals of Occupational Hygiene 54(7).789-798. https://doi.org/10.1093/annhyg/meq044.

12 According to Gralton et al. (2011), particles generated from respiratory activities range from 0.01 up to 500 microns, with a particle size range of 0.05 to 500microns associated with infection. Gralton et al. 2011. The role of particle size in aerosolised pathogen transmission: A review. Journal of Infection 62.1-13. DOI:10.1016/j.jinf.2010.11.010.

13 Davies et al. 2013. Testing the efxcacy of homemade masks: Would they protectin an inyuenza pandemic? Disaster Medicine and Public Health Preparedness7(4).413-418. DOI: 10.1017/dmp.2013.43.

14 van der Sande et al. 2008. Professional and home-made face masks reduceexposure to respiratory infections among the general population. PLOS ONE3(7):e2618. DOI: 10.1371/journal.pone.0002618.

experiment tested the effectiveness of the three masks at reducing emissions from a simulation dummy head that produced uniform "exhalations." It found that cloth masks reduced emitted particles (leakage)by one-fifth, surgical masks reduced it by one-half, and N95-equivalentmasks reduced it by two-thirds.

MacIntyre et al. (2015)15 conducted a randomized controlled trial comparing infection rates of 1,607 hospital health care workers wearing cloth (two layers, made of cotton) or medical masks (three layers, made of non-woven material) while performing their normal tasks. Workers who used cloth masks experienced much higher rates of influenza-like illness (relative risk = 13.00, 95% confidence interval 1.59 to 100.07). This study measured the protective effect for the wearer, rather than the protection of others from the wearer, and did not include a condition with individuals wearing no masks.

EFFECT ON USERS' RISK BEHAVIOR

In our rapid review, we found no studies of the effects of wearing masks on users' behavior. Speculatively, for some users, masks could provide a constant reminder of the importance of social distancing, as well as signal its importance to others, strengthening the social norm of social distancing. Conversely, for some users, masks might "crowd out" other precautionary behaviors, giving them a feeling that they have done enough to protect themselves and others. Prior research, conducted in less intense settings, could support either speculation. Focused research could help determine when precautionary behaviors reinforce or displace one another.

It is critically important that any discussion of homemade fabric masks reinforce the central importance of physical distancing and personal hygiene (frequent handwashing) in reducing spread of infection.

CONCLUSIONS

There are no studies of individuals wearing homemade fabric masks in the course of their typical activities. Therefore, we have only limited, indirect evidence regarding the effectiveness of such masks for protecting others, when made and worn by the general public on a regular basis. That evidence comes primarily from laboratory studies testing the effectiveness of different materials at capturing particles of different sizes. The evidence from these laboratory filtration studies suggests that such fabric masks may reduce the transmission of larger respiratory droplets. There is little evidence regarding the transmission of small aerosolized particulates of the size potentially exhaled by asymptomatic or presymptomatic individuals with COVID-19. The extent of any protection will depend on how the masks are made and used. It will also depend on how mask use affects users' other precautionary behaviors, including their use of better masks, when those become widely available. Those behavioral effects may undermine or enhance homemade fabric masks' overall effect on public health. The current level of beneift, if any, is not possible to assess

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15 MacIntyre et al. 2015. A cluster randomised trial of cloth masks compared with medical masks in healthcare workers. BMJ Open 5(4):e006577. DOI:10.1136/bmjopen-2014-006577.

Research could provide firmer answers by assessing the effectiveness of such fabric masks, as made and used by the general public. That research would have the goals of providing the public with (1) usable instructions on how to make, fit, use, and clean homemade fabric masks; (2) estimates of the protection that such masks afford users and others in different environments (e.g., where the likelihood of contact is higher, like grocery stores, compared to wearing masks all of the time); and (3) effective reinforcement of other precautionary behaviors. That research could provide policy makers with estimates of the net effect of encouraging the use of homemade fabric masks on public health, with realistic estimates of how such masks will be made and used, as well as how they will affect other precautionary behaviors of users and others who observe and interact with them.

My colleagues and I hope this input is helpful to you as you continue to guide the nation's response in this ongoing public health crisis.

Respectfully, Richard Besser, M.D. Member Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats Baruch Fischhoff, Ph.D. Member Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats

APPENDIX

Authors and Reviewers of This Rapid Expert Consultation1

This rapid expert consultation was prepared by staff of the National Academies of Sciences, Engineering, and Medicine, and members of the National Academies' Standing Committee on Emerging Infectious Diseases and 21st Century Health Threats: Richard Besser, Robert Wood

Johnson Foundation, and Baruch Fischhoff, Carnegie Mellon University. The following subject-matter experts also provided input: Sundaresan Jayaraman, Georgia Tech, and Michael Osterholm, University of Minnesota. Harvey Fineberg, chair of the Standing Committee, approved this document. The following individuals served as reviewers: Ned Calonge, The Colorado Trust; Robert Hornik, University of Pennsylvania; Thomas Inglesby, Johns Hopkins Bloomberg School of Public Health Center for Health Security; and Grace Lee, Stanford University. Bobbie A. Berkowitz, Columbia University School of Nursing; Ellen Wright Clayton, Vanderbilt University Medical Center; and Susan Curry, University of Iowa, served as arbiters of this review on behalf of the National Academies' Report Review Committee and their Health and Medicine Division.

Exhibit #15

Address of the Chair of AcademyHealth

Why Truth Matters: Research versus Propaganda in the Policy Debate

Judith Feder

I begin my remarks with a confession: I wrote the title of my talk—"Why Truth Matters"—before I wrote the talk. I know such behavior is neither unique nor egregious. But it has caused me some anxiety. First came the challenge from my son, who is studying philosophy. To paraphrase his reaction: "Mom—What are you thinking? Surely you know there's no such thing as truth." Second came my fear that some in the audience, recalling my political experience, might leap to the microphone saying: "This woman claims to know what truth is?" And third—worst of all—came my conversation with myself, when (in the middle of the night, of course), I said: "So, hot shot, why does truth matter in the policy debate?"

I share these anxieties to let you know not only that I've struggled with the question I posed for these remarks, but also that I've resolved my struggle. I do think truth matters and I'm going to explain why. I'll start with a distinction between truth and propaganda, compliments of my son; then, I'll describe how truth operates in the policy process. I'll conclude with why truth matters.

Participants in this year's annual meeting of the Academy have discussed and debated a wide range of health research and policy issues—examining how institutions, individuals, and incentives interact in the delivery and financing of health care. Figuring out how things work is the business of the "academy" writ large and of AcademyHealth. It's this pursuit of knowledge that I'll call "truth."

Fundamental to pursuing truth is to start with a question, rely on intellectually sound techniques and methods to answer it, and report the answer, whatever it may be. The question and even the kinds of evidence brought to bear may be shaped by values. After all, there is no such thing as value-free social science. But in "truthful" research, the answers are what they are, regardless of the researcher's point of view. By contrast, "propaganda" starts with an answer and relies on research not to find out how things work but to prove a predetermined conclusion.[1]

With the difference between truth and propaganda defined, the next question is whether that difference makes any difference in the policy process. My sense is that it's frustratingly hard to see any difference in impact or influence. I'm confident that every researcher in this audience has watched in horror debates on Capitol Hill—each wondering about priorities, about legislation that seems to make no sense, about partisan distinctions that seem to make no difference, about, indeed, ignoring research. It's easy for a researcher to look at politics and conclude, "Why bother?"—that is, that truth, or research, doesn't matter at all. But that conclusion would be wrong. Let me tell you why.

In an analysis that provides a foundation for the study of public policy, John Kingdon identifies three parts of the process of getting items on the political agenda: identification of the policy problem, development of solutions, and debate and decisions about taking policy action.[2] Research—or truth—plays a role in all three. Let's first focus on defining the policy problem. Research may not be definitive here, but it clearly plays a role. Whether the issue is quality (as presented in Don Berwick's keynote address for this meeting), prescription drugs, racial disparities, immunization rates, deaths from AIDS, or a host of other human concerns, research has made an enormous difference in putting problems for people on the policy and political agenda. Research on trends—on health care coverage, health care costs, or other matters of concern—may not be the most exciting of research topics, but it's amazing what data can do to attract political attention. It is politics that determines whether any of these issues will grab the political limelight at any given moment. But it is data and research that determine whether there's something to grab.

What about developing policy solutions? Here's where much of the action is in the research-to-policy connection—measuring how a policy intervention will affect a myriad of behaviors in the health care world. It's a tough task, let's face it, in part because, as researchers, we recognize the enormous uncertainties surrounding any policy intervention. On the issue I concentrate on, for example—health care coverage—questions exist about whether a policy intervention will increase coverage, whether an increase in coverage will improve access to care, and whether improved access to care will lead to better health. There's not always a great scientific base on which to make a case for a specific action. But that's why they pay us the big bucks, and all our truth-telling skills are called into play. We draw on all our evaluation,

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Judith Feder is Chair of AcademyHealth.

assessment, and projection methodologies to estimate an intervention's impacts, incentives, and outcomes. Specifically,

- Who's affected and how?
- Whose behavior will change and how?
- What perverse incentives and unintended consequences (always the researcher's favorite) will emerge?
- How likely is it that the intervention will make matters worse rather than better?

Probably the most frequent impact of answers to these questions is to take some policy proposals off the policy agenda. Although not as satisfying as getting an initiative on the agenda, this impact nevertheless reflects the power of our ability to distinguish what will work from what won't in the policy arena.

And that takes us to the third part of the policy process—the arena of policy action. It's in this arena that we come to the heart of the matter regarding the role of "truth": in the political world, who really cares about what will work and what won't? An answer to this question has to start from the premise that politics is not about truth; it's about values, and interests, and votes, and money. As a card-carrying political scientist, I can tell you, truthfully, that's just how it is.

But politics creates "windows" of opportunity,[3] and in those windows, research provides the tools or the weapons to carry the day. Research is the source for claims regarding the deaths prevented, dollars saved, jobs created, that are the essence of policy advocacy.

So that's how research, or truth, is used in the various parts of the policy process and past leaders of the Academy—Jack Hadley, Diane Rowland, Arnie Epstein—as well as our keynote speaker Don Berwick have given ample evidence of our membership's impact on the policy front.

But I've begged my own question. I didn't ask whether truth plays a role in the policy process. I asked whether truth is more powerful than propaganda in that process—in identifying the problem, developing the solution, or supporting political action.

As an honest woman, I think the answer is no. I can't make the case that truth matters with the argument that truth will triumph over propaganda. As we all know, when the politics are propitious, there may be no need for data to get political action. In defining a policy problem, tragedy will trump research any day as a motivator. Witness the impact of September 11 on public health investment or of nursing home deaths on enforcement of nursing home

regulations. And the policy initiative that results may or may not be what research tells us will work.

In identifying solutions, uncertainty is intrinsic to the research enterprise. The fact is that researchers disagree—in my issue area, health insurance, for example, on "take-up rates," "employer dropping," price, and behavior in the health insurance market and a host of other factors critical to estimating the impact of a policy proposal. Even though we all agree on the importance of subsidies to expanding health insurance coverage, we disagree about the evidence and the values embodied in different strategies to provide those subsidies.

In the political debate, sadly, a bad study can be as powerful as a good one. The press and politicians tout numbers and outcomes regardless of their intellectual credibility. Even a bad study provides cover—a rationale for a particular vote—and cover may be all a politician is actually seeking.

I don't believe this is a terribly sophisticated argument. And, if I'd looked a little harder, maybe I'd see that where researchers do agree, or over time, that truth really does overcome propaganda. But given the nature of politics, I remain a skeptic.

In my view, the case for truth rests somewhere other than in its victory—specifically, in the integrity and purpose of the researchers who pursue it. As members of academe, we are, after all, not primarily in the business of politics. We're in the business of truth. We're in it because we like the challenge of figuring out how things work and because we care not just about winning a political battle but about generating and using truth to make policy that will promote whatever values we hold dear. Indeed, the issue is not so much whether anybody else cares about what policy will work; it's that we care. And we feel an obligation and commitment to make sure that—even if it doesn't triumph—truth is at the table in the political debate.

So what is the take-away message from this conclusion? What does it say about what each of us does? It depends upon how researchers, as individuals, view the political process. Some in our community don't really want to be part of that process. For this group, I have two thoughts. First, though you don't need my permission, I think that's fine. Not every researcher has to commit to policy work. A division of labor makes sense, and some of us like participating in the political process more than others. Those of us who do will be happy to use your research. Indeed, Academy staff are primed to share your research with the policy community.

But my second thought to that group is not to discount or ignore politics just because you don't want to participate. What your research shows matters

to people—to their health and financial well-being, to the nature of the society in which they live, to the distribution of resources in that society, and to the effectiveness of the private and public institutions that shape many of its activities. Powerful stakeholders are well aware of these implications. Even if you don't use your research in the political arena, it will be used by others, and used in ways and for ends that you may not support. It behooves you always to consider how your research might be used and to write in a way that minimizes its misuse.

For those who want to participate in policy politics, I have a different set of suggestions.

- Pick your research questions not only based on what is but on what ought to be on the political agenda. Your best work comes out of your own enthusiasm, and you never can tell when that policy window will open.
- Use your research to tell a story—the valuable advice I got while writing my dissertation. If you don't know what your story is—if you can't answer the "so what?" question—you simply haven't done your job.
- Beware of traps. The line between research and propaganda gets fuzzy when you want to play in the political process. The push for certainty in an uncertain environment—for truth about a future that is, truthfully, unknowable—is powerful. Speaking truth to power, as Aaron Wildavsky defined the role of a policy analyst, is not always pleasurable. But commitment to truth under pressure is a measure of your own integrity.

The bottom line? As members of academe and AcademyHealth, pursuit of truth is our hallmark. We have reason to be proud of what we do. Just as politics is not about the pursuit of truth, the pursuit of truth is not about politics. We pursue it because it's the right thing to do.

NOTES

1. For thoughts on this distinction, see "The Use and Abuse of History," Chapter 4 in *Declarations of Independence: Cross-examining American Ideology*, by Howard Zinn (New York: Harper Perennial, 1991).
2. John W. Kingdon. 1995. *Agendas, Alternatives, and Public Policies*. New York: HarperCollins College Publishers.
3. See Kingdon.

Exhibit #16

U.S. FOOD & DRUG ADMINISTRATION

April 24, 2020

To: Manufacturers of Face Masks;
Health Care Personnel;
Hospital Purchasing Departments and Distributors; and
Any Other Stakeholders.

On April 18, 2020, in response to concerns relating to insufficient supply and availability of face masks,[1,2] the U.S. Food and Drug Administration (FDA) issued an Emergency Use Authorization (EUA) authorizing the use of face masks for use by members of the general public, including health care personnel (HCP)[3] in healthcare settings as personal protective equipment (PPE), to cover their noses and mouths, in accordance with Centers for Disease Control and Prevention (CDC) recommendations, to prevent the spread of the virus called severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) during the Coronavirus Disease 2019 (COVID-19) pandemic, pursuant to section 564 of the Federal, Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3).

On February 4, 2020, pursuant to Section 564(b)(1)(C) the Act, the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security or the health and security of United States

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[1] A face mask is a device, with or without a face shield, that covers the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels. It includes cloth face coverings as a subset. It may be for single or multiple uses, and if for multiple uses it may be laundered or cleaned. There are many products marketed in the United States as "face masks" that offer a range of protection against potential health hazards. Face masks are regulated by FDA when they meet the definition of a "device" under section 201(h) of the Act. Generally, face masks fall within this definition when they are intended for a medical purpose. Face masks are regulated under 21 CFR 878.4040 as Class I 510(k)-exempt devices (non-surgical masks).

[2] Surgical masks are not covered within the scope of this authorization. Surgical masks are masks that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials and are regulated under 21 CFR 878.4040 as class II devices requiring premarket notification. Additionally, these masks meet certain fluid barrier protection standards and Class I or Class II flammability tests. More information on the distinction is provided in FDA guidance, titled "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency" available at https://www.fda.gov/media/136449/download.

[3] HCP refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These HCP include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

citizens living abroad, and that involves the virus that causes COVID-19.[4] Pursuant to Section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, due to shortages during the COVID-19 pandemic, subject to the terms of any authorization issued under that section.[5]

On April 24, 2020 in response to questions and concerns that have been received by FDA since issuance of the April 18, 2020 letter of authorization and having concluded that revising the April 18, 2020 EUA is appropriate to protect the public health or safety under section 564(g)(2)(c) of the Act (21 U.S.C. § 360bbb-3(g)(2)(c)), FDA is reissuing the April 18, 2020 letter in its entirety with amendments[6] incorporated. Specifically, FDA is clarifying through this re-issued letter that facemasks, including cloth face coverings, are authorized to be used by HCP only as source control[7,8] in accordance with CDC recommendations under this EUA.[9] As stated in the April 18 letter, face masks are authorized for use by the general public to cover their noses and mouths, in accordance with CDC recommendations.

Having concluded that the criteria for issuance of this authorization under Section 564(c) of the Act are met, I am authorizing the emergency use of face masks for use in accordance with CDC recommendations, as described in the Scope of Authorization (Section II) and pursuant to the Conditions of Authorization (Section IV) of this letter.

For the most current CDC recommendations on the use of face masks by the general public during COVID-19, please visit CDC's webpage: Recommendation Regarding the Use of Cloth Face Coverings, Especially in Areas of Significant Community-Based Transmission For the most recent recommendations on use of face masks by HCPs in a healthcare setting, see: Strategies to Optimize the Supply of PPE and Equipment.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of face masks in accordance with CDC recommendations as source control as described in the Scope of Authorization (Section II) to

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[4] U.S. Department of Health and Human Services, Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3. 85 FR 7316 (February 7, 2020)

[5] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 17335 (March 27, 2020).

[6] The amendments to the April 18, 2020 letter clarify that the eligible facemasks are to be used for source control only, and are not personal protective equipment, meaning they are not a substitute for filtering face piece respirators or for surgical face masks. This reissued EUA does not change any aspects of the April 18, 2020 letter with respect to the use of face masks by the general public.

[7] Source control refers to the use of a facemask or cloth face covering over the mouth and nose to contain that individual's respiratory secretions to help prevent transmission from infected individuals who may or may not have symptoms of COVID-19.

[8] https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html

[9] In addition, health care employers should refer to standards of the Occupational Safety and Health Administration (OSHA) that apply to PPE to protect workers and infectious disease hazards. *See* 29 CFR 1910 subpart I.

help prevent spread of the virus during the COVID-19 pandemic meets the criteria for issuance of an authorization under Section 564(c) of the Act, because I have concluded that:

1. SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the authorized face masks may be effective as source control to help prevent the spread of SARS-CoV-2 by infected individuals who may or may not have symptoms of COVID-19 during the COVID-19 pandemic, and that the known and potential benefits of face masks, when used in accordance with the scope of this authorization (Section II), outweigh the known and potential risks of such product; and

3. There is no adequate, approved, and available alternative to the emergency use of face masks for source control by the general public and for HCPs to help prevent the spread of the virus due to face mask shortages during the COVID-19 pandemic.[10,11]

II. Scope of Authorization

I have concluded, pursuant to Section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of face masks, including cloth face coverings, as source control for use by members of the general public, as well as HCP in healthcare settings, to cover their noses and mouths, in accordance with CDC recommendations, to help prevent the spread of the SARS-CoV-2 during the COVID-19 pandemic. The facemasks are not intended to be used by HCPs as PPE, meaning they are neither substitutable for respiratory protective devices such as filtering face piece respirators, nor for surgical face masks. This use is consistent with face masks regulated as Class I 510(k)-exempt face masks under 21 CFR 878.4040.

Authorized Face Masks

Face masks are authorized under this EUA when they are intended for use as source control, by members of the general public as well as HCPs in healthcare settings, to cover their noses and mouths, in accordance with CDC recommendations, to help prevent the spread of SARS-CoV-2 during the COVID-19 pandemic. Authorized face masks must meet the following requirements:

1. The product is labeled accurately to describe the product as a face mask and includes a list of the body contacting materials (which does not include any drugs or biologics);

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[10] No other criteria of issuance have been prescribed by regulation under Section 564(c)(4) of the Act.

[11] Providing authorization for the introduction into interstate commerce of face masks by manufacturers that do not customarily engage in the manufacture of medical devices helps meet the needs of the healthcare system. In addition, increased availability of face masks helps meet the needs for source control for the general population, reserving FDA-cleared surgical masks and FDA-cleared or -authorized N95 and N95 equivalent Face Filtering Respirators for use by HCP. Providing HCP who are on the forefront of the COVID-19 response with sufficient PPE is necessary in order to help prevent HCP exposure to pathogenic biologic airborne particulates during the COVID-19 pandemic.

2. The product is labeled accurately so that it does not claim to be intended for use as a surgical mask or to provide liquid barrier protection;
3. The product labeling includes recommendations against use in a clinical setting where the infection risk level through inhalation exposure is high;
4. The product is not labeled in such a manner that would misrepresent the product's intended use; for example, the labeling must not state or imply that the product is intended for antimicrobial or antiviral protection or related uses or is for use such as infection prevention or reduction;
5. The product is not labeled as a respiratory protective device, and therefore should not be used for particulate filtration; and
6. The product is not labeled for use in high risk aerosol generating procedures.[12]

Manufacturers of face masks that are used as described above and meet the above requirements (i.e., are within this section (the Scope of Authorization, Section II)) do not need to take any action, other than complying with the Conditions of Authorization (Section IV) to be authorized under this EUA. FDA's posting and public announcement of this EUA at https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization, serves as face mask manufacturers' notification of authorization.

I have concluded, pursuant to Section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of face masks as described within this section (the Scope of Authorization, Section II), outweigh the known and potential risks of such products.

I have concluded, pursuant to Section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that face masks may be effective as described within this section (the Scope of Authorization, Section II) of this letter, pursuant to Section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I of this letter, and concludes that face masks (as described in this section, the Scope of Authorization, Section II), meet the criteria set forth in Section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of face masks must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section IV). Subject to the terms and conditions of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under Section 564(b)(1), face masks, as source control, are authorized for use by members of the general public, as well as HCPs in healthcare settings, to cover their noses and mouths, in accordance with CDC recommendations, to help prevent the spread of SARS-CoV-2 during the COVID-19 pandemic.

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[12] Examples of aerosol generating procedures in healthcare settings may be found at https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-faq.html

III. Waiver of Certain FDA Requirements

Pursuant to Section 564(e)(3) of the Act, with respect to the emergency use of a product for which an authorization under this section is issued, FDA may waive or limit, to the extent appropriate given the circumstances of the emergency, requirements regarding good manufacturing practice otherwise applicable to the manufacture, processing, packing, or holding of products subject to regulations under this Act, including such requirements established under sections 520(f)(1). FDA grants that waiver, including the quality system requirements under 21 CFR Part 820 and labeling requirements under the FD&C Act and FDA regulations, including unique device identification requirements in 21 CFR Part 830 and 21 CFR 801.20, except that face masks must include the labeling elements specified in the Conditions of Authorization (Section IV).

IV. Conditions of Authorization

Pursuant to Section 564(e) of the Act, I am establishing the following conditions to this authorization:

Manufacturers and Distributors of Authorized Products[13]

A. Manufacturers and Distributors will make face masks available with labeling that includes a description of the product as a face mask, including a list of the body contacting materials (which does not include any drugs or biologics).

B. Manufacturers and Distributors of authorized products shall not label the product: 1) as a surgical mask, to provide liquid barrier protection; 2) for use in a clinical setting where the infection risk level through inhalation exposure is high; 3) for antimicrobial or antiviral protection or related uses or uses for infection prevention or reduction or related uses; 4) as a respiratory protective device; or 5) for high risk aerosol-generating procedures.

C. Manufacturers must make the required labeling available to each end user or end user facility (each hospital) in hard copy or in an alternative format (e.g., electronic labeling on the manufacturer's website). Instructions on how to access the labeling if provided in an alternative format must be available to each end user or end user facility.

D. Manufacturers and Distributors will include instructions for recommended cleaning and/or disinfection materials and processes, if applicable, for their authorized product(s). Manufacturers must provide these instructions, if applicable, to each end user or end user facility (e.g., each hospital) in hard copy or in an alternative format (e.g., electronic instructions). Instructions on how to access the labeling if provided in an alternative format must be available to each end user or end user facility.

[13] The requirements under 21 CFR Part 806 (Reports of Corrections and Removals) and 21 CFR Part 807 (Registration and Listing) do not apply to products authorized under an EUA. As such, compliance with these regulations are not required under this EUA.

E. Manufacturers will have a process in place for reporting adverse events of which they become aware to FDA under 21 CFR Part 803. Adverse events of which the manufacturer becomes aware will be reported to FDA. See FDA's webpage "Medical Device Reporting (MDR): How to Report Medical Device Problems"[14] for reporting requirements and procedures.[15]

F. Manufacturers and distributors will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

G. Through a process of inventory control, manufacturers and distributors will maintain records of the entities to which they distribute the face masks and the numbers of each such product they distribute.

H. Manufacturers and distributors are authorized to make available additional information relating to the emergency use of the product that is consistent with, and does not exceed, the terms of this letter of authorization.

Conditions Related to Advertising and Promotion

I. All printed matter, including advertising and promotional materials, relating to the use of the authorized face mask shall be consistent with the labeling elements listed in Section II of this EUA, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

J. No printed matter, including advertising or promotional materials, relating to the use of the authorized face mask may represent or suggest that such product is safe or effective for the prevention or treatment of patients during the COVID-19 pandemic.

K. All advertising and promotional descriptive printed matter relating to the use of the product shall clearly and conspicuously state that

- The product has not been FDA cleared or approved
- The product has been authorized by FDA under an EUA for use as source control by the general public as well as by HCP in healthcare settings as to help prevent the spread of infection or illness during the COVID-19 pandemic.
- This product is authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices, including alternative products used as medical devices,

[14] FDA guidance, titled "Medical Device Reporting (MDR): How to Report Medical Device Problems" is available at https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

[15] Also refer to FDA guidance, titled "Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic" available at https://www.fda.gov/media/72498/download.

during the COVID-19 outbreak, under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1) unless the authorization is terminated or revoked sooner.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying this authorization is terminated under Section 564(b)(2) of the Act or the EUA is revoked under Section 564(g) of the Act.

Sincerely,

/S/

RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Exhibit #17

Contains Nonbinding Recommendations

Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)

Guidance for Industry and Food and Drug Administration Staff

May 2020

This document supersedes "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)" issued April 2020.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Office of Product Evaluation and Quality (OPEQ)

Contains Nonbinding Recommendations

Preface

Public Comment

This guidance is being issued to address the Coronavirus Disease 2019 (COVID-19) public health emergency. This guidance is being implemented without prior public comment because the Food and Drug Administration (FDA or the Agency) has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

Comments may be submitted at any time for Agency consideration. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to https://www.regulations.gov. All comments should be identified with the docket number FDA-2020-D-1138 and complete title of the guidance in the request.

Additional Copies

Additional copies are available from the FDA webpage titled "Coronavirus Disease 2019 (COVID-19)," *available at* https://www.fda.gov/emergency-preparedness-and-response/mcm-issues/covid-19-related-guidance-documents-industry-fda-staff-and-other-stakeholders, and the FDA webpage titled "Search for FDA Guidance Documents," *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive an additional copy of the guidance. Please include the document number 20018 and complete title of the guidance in the request.

Questions

For questions about this document, contact 1-888-INFO-FDA or CDRH-COVID19-SurgicalMasks@fda.hhs.gov

Contains Nonbinding Recommendations

Table of Contents

Contains Nonbinding Recommendations

Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

FDA plays a critical role in protecting the United States from threats such as emerging infectious diseases, including the Coronavirus Disease 2019 (COVID-19) pandemic. FDA is committed to providing timely guidance to support response efforts to this pandemic.

FDA is issuing this guidance to provide a policy to help expand the availability of general use face masks for the general public and particulate filtering facepiece respirators (including N95 respirators) for healthcare personnel (HCP)[1] for the duration of the COVID-19 public health emergency.

This policy is intended to remain in effect only for the duration of the public health emergency

[1] As used in the three EUAs for filtering facepiece respirators in effect at the time of this guidance, healthcare personnel (HCP) refers to all paid and unpaid persons serving in healthcare settings who have the potential for direct or indirect exposure to patients or infectious materials, including body substances (e.g., blood, tissue, and specific body fluids); contaminated medical supplies, devices, and equipment; contaminated environmental surfaces; or contaminated air. These healthcare personnel include, but are not limited to, emergency medical service personnel, nurses, nursing assistants, physicians, technicians, therapists, phlebotomists, pharmacists, dentists and dental hygienists, students and trainees, contractual staff not employed by the healthcare facility, and persons not directly involved in patient care, but who could be exposed to infectious agents that can be transmitted in the healthcare setting (e.g., clerical, dietary, environmental services, laundry, security, engineering and facilities management, administrative, billing, and volunteer personnel).

related to COVID-19 declared by the Secretary of Health and Human Services (HHS) on January 31, 2020, effective January 27, 2020, including any renewals made by the HHS Secretary in accordance with section 319(a)(2) of the Public Health Service Act (PHS Act) (42 U.S.C. 247d(a)(2)).

Given this public health emergency, and as discussed in the Notice in the *Federal Register* of March 25, 2020, titled "Process for Making Available Guidance Documents Related to Coronavirus Disease 2019," *available at* https://www.govinfo.gov/content/pkg/FR-2020-03-25/pdf/2020-06222.pdf, this guidance is being implemented without prior public comment because FDA has determined that prior public participation for this guidance is not feasible or appropriate (see section 701(h)(1)(C) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)(1)(C)) and 21 CFR 10.115(g)(2)). This guidance document is being implemented immediately, but it remains subject to comment in accordance with the Agency's good guidance practices.

In general, FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

There is currently an outbreak of respiratory disease caused by a novel coronavirus. The virus has been named "SARS-CoV-2," and the disease it causes has been named "Coronavirus Disease 2019" (COVID-19). On January 31, 2020, the HHS issued a declaration of a public health emergency related to COVID-19 and mobilized the Operating Divisions of HHS.[2] In addition, on March 13, 2020, the President declared a national emergency in response to COVID-19.[3]

FDA believes the policy set forth in this guidance may help address these urgent public health concerns by clarifying the regulatory landscape of face masks and respirators, helping to expand the availability of general use face masks for use by the general public, and of filtering facepiece respirators (including N95 respirators) for use by HCP in healthcare settings.

This document supersedes the guidance, "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised)," issued April 2020. The April 2020 version revised the original guidance, "Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency," issued March 25, 2020, to include face shields and to provide FDA's recommendations regarding alternatives when FDA-cleared or NIOSH-approved N95 respirators are not available. This version includes additional updates regarding alternatives when FDA-cleared or NIOSH-approved N95 respirators are not available and removes FDA's prior recommendations regarding emergency use

[2] Secretary of Health and Human Services Alex M Azar, Determination that a Public Health Emergency Exists. (Jan. 31, 2020, renewed April 21, 2020), *available at* https://www.phe.gov/emergency/news/healthactions/phe/Pages/default.aspx.
[3] Proclamation on Declaring a National Emergency Concerning the Novel Coronavirus Disease (COVID-19) Outbreak (Mar. 13, 2020), *available at* https://www.whitehouse.gov/presidential-actions/proclamation-declaring-national-emergency-concerning-novel-coronavirus-disease-covid-19-outbreak/.

authorizations (EUAs) for decontamination of face masks and filtering facepiece respirators.[4]

III. Scope

There are many products marketed in the United States as "face masks" that offer a range of protection against potential health hazards. Face masks[5] and respirators are regulated by FDA when they meet the definition of a device under section 201(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). Generally, face masks fall within this definition when they are intended for a medical purpose, including for use by HCP.[6] Face masks that are not intended for a medical purpose are not medical devices, as described in further detail below. FDA-regulated face masks and respirators are listed in Table 1:

Table 1

Classification Regulation	Device Type	Product Code[7]
21 CFR 878.4040	Mask, Surgical	FXX
	Pediatric/Child Facemask	OXZ
	Accessory, Surgical Apparel (Face Shield)[8]	LYU
	Surgical mask with antimicrobial/antiviral agent	OUK
	Respirator, Surgical	MSH
	N95 Respirator with Antimicrobial/Antiviral Agent	ONT
21 CFR 880.6260	N95 Respirator with Antimicrobial/Antiviral Agent for Use by the General Public in Public Health Medical Emergencies	ORW
21 CFR 880.6260	Respirator, N95, for Use by the General Public in Public Health Medical Emergencies	NZJ

[4] Concurrently with issuance of this revised guidance, the FDA is issuing the guidance, "Recommendations for Sponsors Requesting EUAs for Decontamination and Bioburden Reduction Systems for Surgical Masks and Respirators During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency."

[5] FDA also considers face mask and surgical mask accessories that are intended to help hold the mask to the face (e.g., surgical mask strap holders, tension release bands) to fall within the scope of this guidance. Respirator accessories are not included in the scope of this guidance.

[6] As used in this guidance "intended for a medical purpose" means that the device is intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease and, therefore, meets the definition of "device" set forth in section 201(h) of the FD&C Act.

[7] For more information see the Product Classification Database at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm.

[8] The scope of this guidance is limited to face shields and their accessories that are intended to help to hold the face shield to the face under product code LYU, "Accessory, Surgical Apparel." Face shields and their accessories that are intended to help to hold the face shield to the face are class I devices and are exempt from premarket notification requirements under 510(k) of the FD&C Act. *See* 21 CFR 878.4040. Face shields combined with devices other than a face mask (e.g., a gown, hood or toga) are not within the scope of this guidance. *See* "Enforcement Policy for Gowns, Other Apparel, and Gloves During the Coronavirus Disease (COVID-19) Public Health Emergency" *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-gowns-other-apparel-and-gloves-during-coronavirus-disease-covid-19-public-health.

This policy does **NOT** apply to other types of masks including but not limited to those in Table 2.

Table 2

Classification Regulation	Device Type	Product Code
21 CFR 868.5450	Humidifier, Respiratory Mask	OBN
	Humidifier, Respiratory Gas	BTT
21 CFR 868.5550	Mask, Anesthetic, Gas	BSJ
21 CFR 868.5580	Mask, Oxygen	BYG
21 CFR 868.5600	Mask, Oxygen, Low Concentration, Venturi	BYG
21 CFR 868.5570	Mask, Oxygen, Non-Rebreathing	KGB
21 CFR 868.5905	Resuscitator, Manual, Non Self-Inflating	NHK
	Mask, Ventilator, Non-Continuous, Reprocessed	NMC
21 CFR 868.5560	Strap, Head, Gas Mask	BTK

FDA recognizes that, when personal protective equipment (PPE), such as FDA-cleared surgical masks or respirators, are unavailable, individuals, including HCP, might improvise. FDA does not intend to object to individuals' distribution and use of improvised PPE when FDA-cleared or authorized surgical masks or respirators are not available.

IV. Definitions

For the purposes of this guidance, the following definitions are used.

Face Mask – A mask, with or without a face shield, that covers the user's nose and mouth and may or may not meet fluid barrier or filtration efficiency levels. Face masks are for use by the general public and HCP only as source control in accordance with CDC recommendations.[9,10]

Face Shield - A face shield is a device used to protect the user's eyes and face from bodily fluids, liquid splashes, or potentially infectious materials. Generally, a face shield is situated at the crown of the head and is constructed with plastic to cover the user's eyes and face.

Surgical Mask – A mask that covers the user's nose and mouth and provides a physical barrier to fluids and particulate materials. The mask meets certain fluid barrier protection standards and Class I or Class II flammability tests.[11]

Filtering Facepiece Respirator – A filtering facepiece respirator (FFR) is a device that is a disposable half-face-piece non-powered air-purifying particulate respirator intended for use to cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological airborne particulates.

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[9] Source control refers to the use of a facemask or cloth face covering over the mouth and nose to contain that individual's respiratory secretions to help prevent transmission from infected individuals who may or may not have symptoms of COVID-19.

[10] https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html.

[11] CPSC CS-191-53 Flammability Test Method (16 CFR 1610) Standard for Flammability of Clothing Textiles.

N95 Respirator – A disposable half-mask filtering facepiece respirator (FFR) that covers the user's airway (nose and mouth) and offers protection from particulate materials at an N95 filtration efficiency level per 42 CFR 84.181. Such an N95 FFR used in a healthcare setting is regulated by FDA under 21 CFR 878.4040 (FDA product code MSH) and is either a class II device that is exempt from premarket notification requirements under section 510(k) of the FD&C Act or is a class II cleared device.

NIOSH Approved N95 Respirator – An N95 respirator, approved by NIOSH that meets filtration efficiency level per 42 CFR 84.181.

Surgical N95 Respirator – A disposable FFR used in a healthcare setting that is worn by HCP during procedures to protect both the patient and HCP from the transfer of microorganisms, body fluids, and particulate material at an N95 filtration efficiency level per 42 CFR 84.181. A surgical N95 respirator is regulated by FDA under 21 CFR 878.4040 (FDA product code MSH) and is either a class II device that is exempt from premarket notification requirements under section 510(k) of the FD&C Act or is a class II cleared device.

V. Policy

A. Overview

FDA is taking steps to expand the availability of face masks and respirators and believes the policy set forth in this guidance may help address the urgent public health concerns caused by shortages of such products by taking a risk-based approach and clarifying the policies that FDA intends to apply to masks and respirators, including these products' associated indications and claims.

B. Face Masks, Face Shields, and N95 Respirators Not Intended for a Medical Purpose

Face masks, face shields, and N95 respirators are devices when they meet the definition of a device set forth in section 201(h) of the FD&C Act. Under section 201(h) of the FD&C Act, these products are devices when they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease.

Other face masks, face shields, and FFRs are marketed to the general public for general, non-medical purposes, such as use in construction and other industrial applications. Because they are not intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, FDA device marketing authorization is **not** required, and all the other requirements of the FD&C Act do **not** apply to manufacturers, importers, and distributors of these products.

Face masks, face shields, and respirators are devices when they are intended for a medical purpose, such as prevention of infectious disease transmission (including uses related to COVID-19). Face masks, face shields, and respirators are not devices when they are intended for a non-medical

purpose, such as for use in construction. When evaluating whether these products are intended for a medical purpose, among other considerations, FDA will consider whether:

1) they are labeled or otherwise intended for use by a HCP;
2) they are labeled or otherwise for use in a health care facility or environment; and
3) they include any drugs, biologics, or anti-microbial/anti-viral agents.

C. Face Masks Intended for a Medical Purpose that are NOT Intended to Provide Liquid Barrier Protection

In general, FDA recommends that HCP follow current Centers for Disease Control and Prevention (CDC) guidance regarding personal protective equipment (PPE) that should be used during the COVID-19 outbreak.[12] Health care employers must also comply with standards of the Occupational Safety and Health Administration (OSHA) that require PPE to protect workers and that apply to infectious disease hazards.[13] Face masks are to be used for source control only, and are not personal protective equipment, meaning they are not a substitute for FFRs or for surgical face masks.[14]

In the April 2, 2020 publication of this guidance, FDA provided flexibility regarding distribution and use of face masks without compliance with certain regulatory requirements, including submission of a 510(k) under certain circumstances. FDA's policy was based on the evolving public health emergency and the increased need for devices for source control. In addition to this policy and in response to the shortage of face masks, on April 18, 2020 FDA issued an EUA for certain face masks[15] that FDA determined met the criteria for issuance under Section 564 of the Act. This EUA has succeeded in increasing the availability of face masks for HCP and the general public for use as source control when FDA-cleared face masks are not available.

Wherever possible, HCP and the general public should continue to use FDA-cleared face masks as source control or, when those are not available, face masks authorized under the EUA. However, to help foster the availability of equipment that might offer some benefit to HCP and the general public during the COVID-19 outbreak, FDA is continuing its April 2, 2020 policy regarding face masks, recognizing there is some overlap with the EUA. Thus, for the duration of the public health emergency FDA does not intend to object to the distribution and use of face masks, with or without a face shield (not including respirators), that are intended for a medical purpose (whether used by medical personnel or the general public), without compliance with the following regulatory requirements where the face mask does not create an undue risk in light of the public health emergency: prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81, Registration and Listing requirements in 21 CFR 807, Quality System Regulation requirements in 21 CFR 820, Reports of Corrections and Removals in 21 CFR Part 806, and Unique

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[12] https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhcp%2Finfection-control.html.

[13] *See* 29 CFR 1910 subpart I.

[14] See FDA's EUA for face masks (non-surgical) available at https://www.fda.gov/media/137121/download and FAQs on the Emergency Use Authorization for Face Masks (Non-Surgical) available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-emergency-use-authorization-face-masks-non-surgical.

[15] https://www.fda.gov/media/137121/download.

Device Identification requirements in 21 CFR Part 830 and 21 CFR 801.20. FDA currently believes such devices would not create such an undue risk where:

- The product includes labeling that accurately describes the product as a face mask (as opposed to a surgical mask or FFR) and includes a list of the body contacting materials (which does not include any drugs or biologics);

- The product includes labeling that makes recommendations that would reduce sufficiently the risk of use, for example, recommendations against: use in any surgical setting or where significant exposure to liquid, bodily or other hazardous fluids, may be expected; use in a clinical setting where the infection risk level through inhalation exposure is high; and use in the presence of a high intensity heat source or flammable gas; and

- The product is not intended for any use that would create an undue risk in light of the public health emergency, for example the labeling does not include uses for antimicrobial or antiviral protection or related uses or uses for infection prevention or reduction or related uses and does not include particulate filtration claims.

D. Face Shields Intended for a Medical Purpose

In general, FDA recommends that HCP follow current Centers for Disease Control and Prevention (CDC) guidance regarding PPE that should be used during the COVID-19 outbreak.[16] Health care employers must also comply with standards of the Occupational Safety and Health Administration (OSHA) that require PPE to protect workers and that apply to infectious disease hazards.[17] To help foster the availability of equipment that might offer some benefit to HCP and the general public during the COVID-19 outbreak, for the duration of the public health emergency, FDA does not intend to object to the distribution and use of face shields that are intended for a medical purpose (whether used by medical personnel or the general public), without compliance with the following regulatory requirements where the face shield does not create an undue risk in light of the public health emergency: Registration and Listing requirements in 21 CFR 807, Quality System Regulation requirements in 21 CFR Part 820, Reports of Corrections and Removals in 21 CFR Part 806, and Unique Device Identification requirements in 21 CFR Part 830 and 21 CFR 801.20. FDA currently believes such devices would not create such an undue risk where:

- The product includes labeling that accurately describes the product as a face shield and includes a list of the body contacting materials (which does not include any drugs, or biologics);

- The face shield does not contain any materials that will cause flammability, or the product meets Class I or Class II flammability requirement per 16 CFR 1610 (unless labeled with a recommendation against use in the presence of high intensity heat source or flammable gas);

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[16] https://www.cdc.gov/coronavirus/2019-ncov/infection-control/control-recommendations.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhcp%2Finfection-control.html.

[17] *See* 29 CFR 1910 subpart I.

- The product is not intended for any use that would create an undue risk in light of the public health emergency, for example, the labeling does not include uses for antimicrobial or antiviral protection or related uses or uses for infection prevention or reduction or related uses, or for radiation protection.

E. Surgical Masks Intended to Provide Liquid Barrier Protection

Surgical masks are class II devices that cover the user's nose and mouth and provide a physical barrier to fluids and particulate materials and are tested for flammability and biocompatibility. For the duration of the declared public health emergency, FDA does not intend to object to the distribution and use of surgical masks without compliance with the following regulatory requirements where the surgical mask does not create an undue risk in light of the public health emergency: prior submission of a premarket notification under section 510(k) of the FD&C Act and 21 CFR 807.81, Registration and Listing requirements in 21 CFR 807, Quality System Regulation requirements in 21 CFR 820, Reports of Corrections and Removals in 21 CFR Part 806, and Unique Device Identification requirements in 21 CFR Part 830 and 21 CFR 801.20. FDA currently believes such devices would not create such an undue risk where:

- The product meets fluid resistance testing (liquid barrier performance) consistent with standard ASTM F1862[18] Standard Test Method for Resistance of Medical Face Masks to Penetration by Synthetic Blood (Horizontal Projection of Fixed Volume at a Known Velocity);

- The product meets Class I or Class II flammability requirement per 16 CFR 1610 (unless labeled with a recommendation against use in the presence of high intensity heat source or flammable gas);

- The product includes labeling that accurately describes the product as a surgical mask and includes a list of the body contacting materials (which does not include any drugs or biologics); and

- The product is not intended for any use that would create an undue risk in light of the public health emergency, for example, the labeling does not include uses for antimicrobial or antiviral protection or related uses or uses for infection prevention or reduction or related uses and does not include particulate filtration claims.

[18] For the current edition of the FDA-recognized standard(s) referenced in this document, see the FDA Recognized Consensus Standards Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm. For more information regarding use of consensus standards in regulatory submissions, refer to FDA guidance titled "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.

F. Alternatives When FDA-Cleared or NIOSH-Approved N95 Respirators are Not Available

CDC published on its website Strategies for Optimizing the Supply of N95 Respirators: Crisis/Alternate Strategies,[19] which, as part of a set of crisis management recommendations, identifies alternatives to FDA-cleared or NIOSH-approved N95 respirators approved under standards used in other countries, some of which were evaluated under methods that are similar to NIOSH-approved N95 respirators.

In the April 2, 2020 publication of this guidance, FDA provided flexibility regarding distribution and use of respirators identified in the CDC recommendations without compliance with certain regulatory requirements, including submission of a 510(k) under certain circumstances. FDA's policy was based on the evolving public health emergency and the increasing need for respiratory protection devices for HCP, which was rapidly outpacing the supply of FDA-cleared or NIOSH-approved respirators. The guidance also recommended that importers take appropriate steps to verify the authenticity of products they import.

In addition to this policy and in response to the shortage of respirators, FDA issued emergency use authorizations (EUAs) for certain respirators that FDA determined met the criteria for issuance under Section 564 of the Act.[20] These EUAs have succeeded in increasing the availability of respirators for HCP when FDA-cleared or NIOSH-approved respirators are not available.

Since the April 2, 2020 publication of this guidance, FDA has become aware of concerns regarding the performance of certain respirators based on testing conducted by the CDC.[21] This indicates that greater FDA oversight of respirators that are not FDA-cleared or authorized under an EUA is important to protect the public health. As a result of these changed circumstances, FDA is discontinuing its previous policy from April 2, 2020 under which FDA did not intend to object to the distribution and use of certain respirators that were not FDA-cleared or authorized under an EUA and did not meet other regulatory requirements.

FDA currently believes that FDA-cleared or NIOSH-approved N95 respirators should be used when they are available, but when they are not, FDA recommends using FDA-authorized respirators before any other alternatives. This is consistent with the CDC's approach for optimizing the supply of N95 respirators. FDA does not recommend using a product as a respirator unless it has been FDA-cleared, NIOSH-approved, or authorized by FDA for emergency use as a respirator. Such a product could instead be used as a face mask by the general public and HCP as source control when certain criteria are met under the EUA for face masks.[22] In that case, the product should be labeled accordingly and not used as a respirator.[23]

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[19] https://www.cdc.gov/coronavirus/2019-ncov/hcp/respirators-strategy/crisis-alternate-strategies.html.

[20] See FDA's webpage regarding emergency use authorizations, available at https://www.fda.gov/medical-devices/emergency-situations-medical-devices/emergency-use-authorizations#covid19ppe.

[21] https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html.

[22] https://www.fda.gov/media/137121/download.

[23] Source control refers to the use of a facemask or cloth face covering over the mouth and nose to contain that individual's respiratory secretions to help prevent transmission from infected individuals who may or may not have symptoms of COVID-19. See also https://www.cdc.gov/coronavirus/2019-ncov/hcp/infection-control-recommendations.html.

In addition, FDA notes that HCP should ensure that respirators adequately fit. Hospitals and end users should be aware that it may be difficult to achieve an adequate fit when wearing respirators with ear loops instead of head straps. When proper fit is not achieved for a respirator, it should not be used as a respiratory protective device.

VI. EUAs for Face Masks Intended for a Medical Purpose, Surgical Masks and N95 Respirators

Wherever possible, health care facilities should continue to use FDA-cleared surgical masks and NIOSH-approved and/or FDA-cleared N95 respirators, or better. In response to the COVID-19 pandemic, FDA has also issued EUAs that authorize certain FFRs, including NIOSH-approved FFRs,[24] imported non-NIOSH-approved disposable FFRs from certain jurisdictions excluding China,[25] and non-NIOSH-approved disposable FFRs manufactured in China,[26] for use in healthcare settings by HCP. These EUAs are intended to help increase availability of these devices to front-line personnel during the public health emergency. FDA has also issued an EUA for face masks[27] for use by the general public and HCP as source control.

For devices that do not fall within the scope of these EUAs, FDA is interested in interacting with manufacturers on additional device-specific EUAs. This may include manufacturers of masks and respirators that are not currently legally marketed in the US as well as manufacturers who have not previously manufactured masks or respirators with capabilities to increase supply of these devices.

FDA would find it helpful if such manufacturers (whether foreign or domestic) send FDA the following information to CDRH-COVID19-SurgicalMasks@fda.hhs.gov; FDA believes this information will be valuable in assessing whether the device would be able to meet the EUA requirements. FDA believes that companies may already have available information to help support an EUA request such as the information outlined below. FDA will expeditiously review this information, and other required information,[28] to determine whether the device can be authorized under an EUA.

1) For current face mask and respirator manufacturers whose product(s) are not currently marketed in the US, FDA recommends providing the following information:
    a. General information such as your contact information, name and place of business, email address, and contact information for a U.S. agent (if any) in addition to general information about the device such as the proprietary or brand name, model number, and marketing authorization in your country (or region).
    b. A copy of the product labeling.
    c. Whether the device currently has marketing authorization in another regulatory jurisdiction (including certification number, if available).

[24] https://www.fda.gov/media/135763/download.
[25] https://www.fda.gov/media/136403/download.
[26] https://www.fda.gov/media/136664/download.
[27] https://www.fda.gov/media/137121/download.
[28] See Section 564 of the FD&C Act.

d. Whether the device is manufactured in compliance with 21 CFR Part 820 or ISO 13485: *Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes* or an equivalent quality system and the manufacturer or importer has documentation of such.
e. Description of testing conducted on the device, including any standards met, such as liquid barrier protection, flammability, biocompatibility, and filtration performance, as appropriate. For surgical N95 respirators, FDA recommends including fluid resistance testing (liquid barrier performance).

2) For face mask manufacturers who have not previously been engaged in medical device manufacturing but with capabilities to increase supply of these devices:

FDA welcomes the opportunity to work with manufacturers not previously engaged in medical device manufacturing with the interest and capability to manufacture face masks and respirators. This may include US manufacturers in other manufacturing sectors. These manufacturers should send an email to the address above and describe their proposed approach. FDA intends to work collaboratively with these manufacturers through its EUA process.

For any face mask or FFR (including N95 respirators) issued an EUA, FDA will include appropriate conditions of authorization in accordance with section 564 of the FD&C Act. Although this is a case-by-case determination, based on current information and experience, we will likely include the following conditions:

- Appropriate conditions designed to ensure that HCP administering the device are informed—
  - that FDA has authorized the emergency use of the device;
  - of the significant known and potential benefits and risks of the emergency use of the device, and of the extent to which such benefit and risks are unknown; and
  - of the alternatives to the device that are available, and of their benefits and risks.

- Appropriate conditions designed to ensure that individuals to whom the device is administered are informed—
  - that FDA has authorized the emergency use of the device;
  - of the significant known and potential benefits and risks of the emergency use of the device, and of the extent to which such benefit and risks are unknown; and
  - of the option to accept or refuse administration of the device, of the consequence, if any, of refusing administration of the device, and of the alternatives to the device that are available and of their benefits and risks.

- Appropriate conditions for the monitoring and reporting of adverse events associated with the emergency use of the device. FDA intends to include conditions that are consistent with those promulgated under 21 CFR Part 803.

- For manufacturers of the device, appropriate conditions concerning recordkeeping and reporting, including records access by FDA, with respect to emergency use of the device.

Exhibit #18

web.archive.org/web/20200618113003/https:/www.foxnews.com/media/surgeon-general-explains-masks-public-coronavirus 1/7

https://www.foxnews.com/media/surgeon-general-explains-masks-public-coronavirus

FOX NEWS FLASH
Published March 31
Surgeon general: Data doesn't back up wearing masks in public amid coronavirus pandemic
By **Talia Kaplan | Fox News**

U.S. Surgeon General: 'The data doesn't show' that wearing masks helps people during coronavirus pandemic
U.S. Surgeon General Dr. Jerome Adams explains why the CDC and WHO do not recommend the general public wear masks and how doing so could increase your virus risk
U.S. Surgeon General Jerome Adams said on "Fox & Friends" Tuesday that "the data doesn't show" that wearing masks in public will help people during the coronavirus

Adams, a member of the Trump administration's Coronavirus Task Force, made the comment one day after President Trump said he sees a scenario where all Americans could be expected to wear masks in public "for a short period of time after we get back into gear."
Trump acknowledged on Monday that he did not yet discuss the idea with his task force and said it is "certainly something we could discuss."
"It's important to understand that we are looking at the data every single day and we make the best recommendations to the American people we can based on what we know," Adams said on Tuesday.
"What the World Health Organization [WHO] and the CDC [The Centers for Disease Control and Prevention] have reaffirmed in the last few days is that they do not recommend the general public wear masks."

He then explained the reasons why.

"On an individual level, there was a study in 2015 looking at medical students and medical students wearing surgical masks touch their face on average 23 times," Adams explained. "We know a major way that you can get respiratory diseases like coronavirus is by touching a surface and then touching your face so wearing a mask improperly can actually increase your risk of getting disease."
Adams went on to say that wearing a face mask "can also give you a false sense of security." He added that "you see many of these pictures with people out and about closer than six feet to each other, but still wearing a mask."

He noted that there are also consequences to wearing masks.

"We still have PPE [Personal protective equipment] shortages across the country," Adams noted. "The WHO mentioned this in their statement so we want to make sure we are reserving PPE for

the people who most need it. That's how you are going to get the largest effect because if healthcare workers get sick, they can't take care of you when you get sick."

CORONAVIRUS: WHAT TO KNOW

Last month, Adams said Americans worried about the coronavirus outbreak shouldn't buy face masks to protect themselves against it because the masks are ineffective for those without symptoms -- and the purchases deplete the supplies available for medical professionals.

"Seriously people- STOP BUYING MASKS!" Adams wrote on Twitter, addressing fears over the spread of the virus in the U.S.

"They are NOT effective in preventing general public from catching #Coronavirus, but if healthcare providers can't get them to care for sick patients, it puts them and our communities at risk!"

On Tuesday Adams stressed that people who are sick should wear a mask.

He added, "If you have a mask and it makes you feel better, then by all means wear it, but know that the more you touch your face the more you put yourself at risk and know that right now the data isn't quite there to say that there is a net benefit to the individual of wearing a mask."

Adams also said that N95 respirator masks aren't as effective for the general public as one might think, saying N95 masks "have to get fit-tested."

"As a medical professional, I can't just go out and wear an N95. I have to make sure it's properly fitted and I have the right size in order for it to work properly," he explained.

"There may be a day when we change our recommendations particularly for areas that have large spread going on about wearing cotton masks, but again the data is not there yet," he continued. "We are continuing to follow it."

He added that the CDC is looking at it and "we'll put out new recommendations if the guidance warrants."

Fox News' Brie Stimson contributed to this report.

Talia Kaplan is a reporter for FoxNews.com. Follow her on Twitter @taliakaplan

Exhibit #19

asks and gloves filling streets, safety hazard

April 21, 2020 | 4:57pm

ited on March 29 shows latex plastic gloves among other waste littering the street in Paris on the 13th day of the French he novel coronavirus, COVID-19.

newsletter to get a daily update on the coronavirus pandemic.

Personal protective equipment may keep humans safe, but it's proving destructive to the environment.

Masks and gloves are increasingly becoming common street trash, as Americans don them as safety precautions against COVID-19 and then discard them by the curb. To make matters worse, the PPE litter is more hazardous than normal garbage, as it has a higher risk of spreading the novel coronavirus. The issue has become so widespread, local law enforcement has begun taking a stance against it, with agencies reaching out to area residents to encourage proper disposal.

"We need to contain the spread of COVID-19 and do the right lawful thing by throwing these items in the trash," the Swampscott Police Department in Massachusetts posted to Facebook alongside a photo of a Stop & Shop parking lot littered with PPE. "This is making a bad problem worse and possibly spreading COVID-19 to the people having to pick this trash up."

The first offense for unlawful disposal of trash, the agency warns residents, is fineable up to $5,500.

Other essential workers — in addition to those in sanitation — are also actively worrying about the danger posed by discarded masks and gloves, as they litter the paths to their jobs.

"Thank you so very much for [addressing] this issue," wrote Stop & Shop employee Kathleen Searle Nohelty in response to the police department's post, "I have 5 young children at home, so not only am I putting myself at risk by going to work so they can shop and get what they need, I am also putting my family at risk!"

In New York City, where wearing a face mask on public transit and in crowded areas is now mandatory, the increase in PPE litter has been shockingly apparent. "People are so awful," wrote one observer in an Instagram post of assorted masks and gloves littering Brooklyn's streets.

Not only is the trash a safety issue, a visible eyesore and a trash problem, it also harms the environment in deeper ways, by adding to microplastic pollution.

The PPE is intended to help us fight a public health challenge, not create a plastic pollution problem," Adrienne Esposito, executive director / Citizens Campaign for the Environment, tells CNN.

NHL a step closer to returning to Canada

NYC, state failed to fund nursing home watchdogs, report says

Exhibit #20

ELSEVIER

Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.

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Environmental challenges induced by extensive use of face masks during COVID-19: A review and potential solutions

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ABSTRACT

The ongoing COVID-19 disease significantly affects not only human health, it also affects the wealth of country' economy and everyday routine of human life. To control the spread of the virus, face mask is used as primary personal protective equipment (PPE). Thus, the production and usage of face masks significantly increase as the COVID-19 pandemic still escalating. Further, most of these masks contain plastics or other derivatives of plastics. Therefore, this extensive usage of face masks generates million tons of plastic wastes to the environments in a short span of time. This study aims to investigate the environmental impact induced by face mask wastes and sustainable solution to reduce this waste. An online survey was carried out to identify the types of face mask and number of masks used per week by an individual from 1033 people. Based on this survey and available literature, this study quantifies the amount of plastics waste generated by face masks. However, this survey was limited with certain ages, country and durations (July–August 2020). Thus, the prediction of plastic waste generation, only provide fundamental knowledge about the mask wastes. Results revealed that there is a huge plastic waste remained in land and marine environment in the form of mask waste, which will contribute to micro-plastic pollution. Therefore, this paper also highlights the sustainable approach to the mask production by integrating the use of natural plant fiber in the woven face mask technology to reduce the plastic waste induced by masks. Further, upcycling the mask waste and producing construction materials also discussed.

1. Introduction

The ongoing COVID-19 pandemic significantly induced uncertain environments for every human, business, education, job, and economy of each country. There is no viable meditation to prevent the spread of this deadly coronavirus disease (Ludin and Okotto, 2020). The use of personal protective equipment (PPE), social distance, travel restrictions and lockdown were currently employed to reduce this spreading level of coronavirus (Rubio-Romero et al., 2020; Sun et al., 2020). This ongoing pandemic situation created that wearing mask is must for every human life. There are various types of masks such as surgical , N95 , and commercial fabric/cloth masks used to tackle the ongoing pandemic situation (Fig. 1).

According to the World Health Organization (WHO) study, in USA about 89 million medical masks are anticipated to be required to respond the COVID-19 as this crisis is likely to persist for some time (Sun et al., 2020). Further, the plastic innovation hub has identified that the domestic demand for the mask in UK is around 24.37 billion per year (Liebreich, 2020). As of February 2020, China has raised its daily production of medical masks to 14.8 million. The Japanese ministry of finance, trade, and industry recorded that more than 600 million face masks required per month of April 2020 (Ludin and Okotto, 2020). The increasing use of mask significantly increases the production of mask and it consumes higher amount of energy. A study by Howard et al., 2020a,b shows that a mask production consumes about 10-30 Wh energy and releases 59 g CO_2-eq greenhouse gas to the environment. Further, ever increasing uses of face mask also increase the landfill and medical waste. Most of these face mask wastes contains either polypropylene and/or polyethylene, polyurethane, polystyrene, polycarbonate, polyacrylonitrile, which add plastic or microplastic pollution to the environment (Allen et al., 2020). This indicates that current ongoing pandemic, increases the environmental pollution and negative impact to human and animal health. Therefore, sustainable solutions need to reduce the environmental impacts, while meeting the mask demand.

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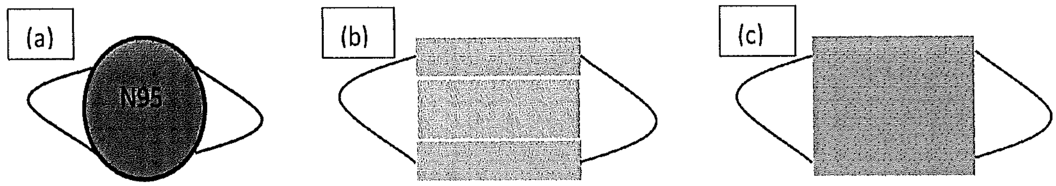

Fig. 1. Example of different type of masks: (a) N95 mask; (b) surgical mask; and (c) cloth mask.

Governments and publics have already begun to explore the alternative solutions including the reuse, reprocessing and disinfection of approved disposable masks, and producing biodegradable masks and homemade or non-certified masks (Rubio-Romero et al., 2020). The effectiveness and impact of these alternatives are not yet understood and practiced by every people. Thus, this study conducts the online survey to identify the mask types, duration and disposal method being employed currently. Furthermore, a comprehensive review was conducted to find the material contents in the mask, impact on the mask wastes and suggest a sustainable upcycling solutions to the mask waste.

2. Data collections

Online survey and literature review were employed to achieve the objectives of this research. Following sub-sections describe the survey and review methods.

2.1. *Online survey*

The data is collected confidentially by conducting an online survey among different age groups (i.e. children (12–15), teenagers (16–25) and adults (26–65)) in many countries, particularly Australia, America, UK, Singapore, Sri Lanka and India. This survey was performed on a total of 1033 individuals for a period of one month (5th July 2020 – 6th August 2020) at COVID-19 pandemic outbreak. In this survey, the questions were focusing following parameters: the types of mask (i.e. surgical mask, N95 mask, cloth mask or both); the amount of masks usage per week; and methods of mask disposal (i.e. wash and dispose, flush in toilets, put in appropriate bin, burning and throw away). The aim of survey is identifying the mask waste generation and provide the fundamental information about effect of the mask waste to the environment. Due to this, the survey did not focus mask waste generation by gender basis (male/female). This limitation could be creating the variation in the amount of mask waste generation. However, finding of this study provide the fundamental knowledge of mask waste generation, which will help to develop the waste control and management policies.

2.2. *Literature review*

The data collection approach of the current study was focused on the review of journal articles related to rapidly growing COVID-19. The data and knowledge on this particular topic are outstanding, showing the severity of the pandemic crisis. Such information is collected not only from scientific literature, but also from numerous reliable online resources, journals, and policy and media reports. The literature was gathered from 2nd February 2020 (at the peak of the first wave of COVID-19 pandemic) until the completion of this review (30th November 2020). The data collection concentrated on a following categories of: (a) precautionary measures used to monitor the forms of COVID-19; (b) the components of the mask; (c) problems relating to the disposal of the mask; (d) and sustainable solutions to address the effect of waste mask.

Two reliable and detailed databases such as Scopus (scopus.com) and Web of Science (webofscience.com) were used to search for the relevant topics. As they provide high coverage of similar papers to the subject of this review and minimize the risk of missing any relevant document. To start with the searching process, a keyword of "COVID-19 or COVID 19" from 2014-2020 was used to develop the final search criteria. The initial results of this search through Scopus and Web of Science (WoS) databases were 26920 and 48406, respectively. Additional limits were given for filtering the quantity of the publications to exclude the irrelevant sources. In that way, the findings decreased to 415 for Scopus and 19 for WoS using key terms such as "COVID-19" AND "Masks" AND "Wastes". In addition, the results were restricted to 131 and 7 journal articles in Scopus and WoS, respectively by using the keywords "COVID-19" AND "Masks" AND "wastes" AND "Environmental" as shown in Fig. 2.

3. Survey results and discussion

Survey results and current issue from the mask waste are presented in the following sections.

3.1. *Survey results*

The data obtained from the online survey was confidentially analyzed in age-wise. Fig. 3 shows the percentage of people who participated in the online survey with different age group. For this survey people with age of 26–45 show more interested to participate .

Fig. 4 shows that about 80% of people always wear masks and about 16% people occasionally wear the mask. This indicates that about 96% of individuals understand the importance of wearing the mask during the pandemic. However, 3% of them rarely used the mask, which may be due to lack of awareness and given less importance of the situation. About 1% of people have never used the mask due to their pre-existing medical condition.

The type of masks used by people who participate in the survey was shown in Fig. 5. This figure indicates that highest population (i.e. 40%) of people are used surgical mask for their personal safety. Whilst, the cloth mask is the second highest for use (34%) as it's cheaper than N95 mask and also be self-made. The N95 mask is highly recommended by WHO, only about 9% people use it as it is expensive than other mask types.

Fig. 6 shows the quantity of waste mask generated by a person per week. This quantification may varies depending on the duration of mask usage, type of mask, degree of people's hygiene, place visited, etc. However, the results from this survey illustrate the fundamental quantification value of mask waste. The survey reveals that more than 25% of people generate 5 masks waste per week. Consequently, at least one mask waste was created by an individual per day.

Mask wastes generated from each country (i.e. Sri Lanka, India, Australia, Singapore, UK and USA) was derived and shown in Fig. 7. This was calculated based on the minimum (i.e. 1) and maximum (i.e. 5) number of masks used by individual (Fig. 6) with the population of people at age between 16 and 65, which were obtained from census data (Clark, 2020; Lam, 2020; Hirschmann, 2020; Plecher, 2020a,b,c). Fig. 7 shows the fundamental idea of mask waste generation per week from Sri Lanka, India, Australia, Singapore, UK and USA. During this peak of the first wave of COVID-19 crisis most of these countries are went under lock down. Hence, the transportation in public and private vehicles, walking was very less, which may have affected the lower percentage of mask usage per week. Therefore, if the usage of mask is con-

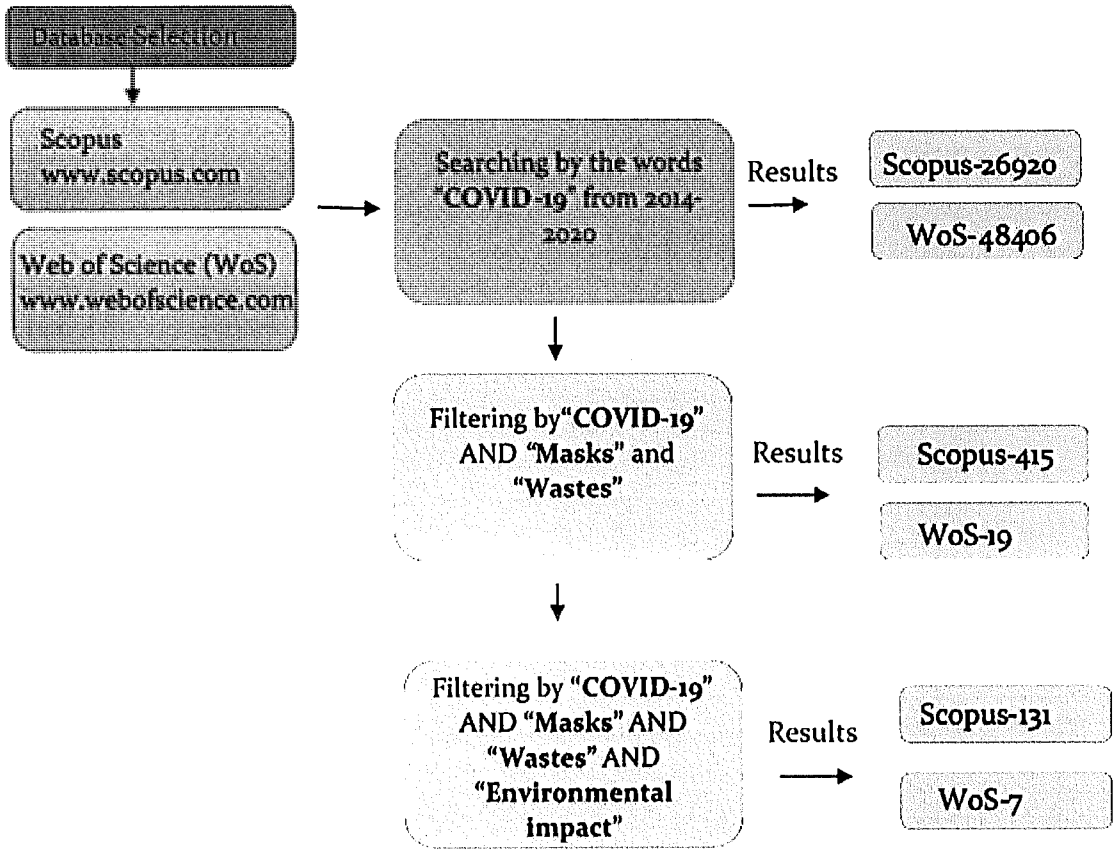

Fig. 2. Summary of total number of reviews.

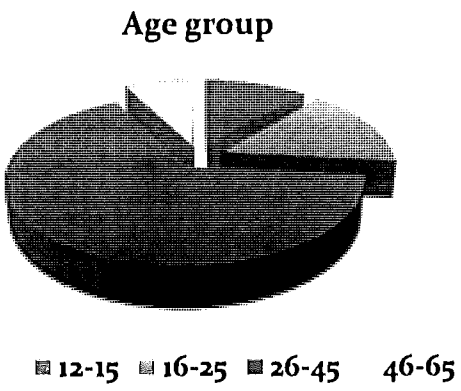

Fig. 3. Different age group people who participated in the online survey.

sidered worldwide with the whole population, it is expected to reach the peak level, which will eventually create a significant amount of plastic waste to the environment.

A study by Aragaw et al. (2020) highlighted that the amount of polypropylene in surgical mask and N95 mask are 4.5 g and 9 g, respectively. Total maximum and minimum amount of polypropylene generated per week from different countries were calculated based on the mask wastes generation per week (Fig. 2). Fig. 3 shows that minimum about 2.5 kt, 0.6 kt, 0.04 kt plastic (i.e. polypropylene) waste were generated, respectively from India, USA, Australia per week. This indicates that this Covid-19 pandemic will impact not only the health and economy, but it will also impact the sustainability of environment.

In order to identify the mask disposal method, the survey question was generated with six general disposal methods: 1) disposed into the mixed waste bin; 2) disposed into the hazardous waste bin; 3) burning; 4) flush in toilets; 5) wash and disposed into mixed waste bin; and 6) throw away. Fig. 4 shows that about 34% and 11% individuals dispose the mask as the mixed waste and hazardous waste, respectively. This indicates that about 45% of them appear to be extremely responsible for the solid waste that they produce. Whereas 19% individuals recklessly throw away the face masks in the street and 12% of people are wash and dispose the mask. This has the potential to create the environmental issues due to its indecomposable nature. Consequently, has high possibilities in creating a future global warming issue. About 3% of people flush the mask in toilets while 10% people burn the mask. This 10% of individuals are responsible for the contamination of the air by the releasing adverse compounds into the atmosphere. Ultimately, this phenomenon could create chronic respiratory illness (Stafford and Jones, 2019).

Further, if the prevailing pandemic situation is to be continued, the people should adapt to live with the safety precaution, which can give them a healthy life. Thus, the mask production will be significant and increase the mask waste in near future. The mask is made of different types of plastic, which is not decomposable, and it induce the negative impact on the environments. Therefore, without disrupting the economy, any innovative steps can be taken with respect to the environment and the social well-being of people. On the other hand, instead of using different types of plastic raw material, steps should be taken to replace some decomposable raw material in production of face masks. In addition, the waste mask can be recycled by different methodologies and used as a supplementary material in any innovative products such as construction materials.

3.2. Material contents in the masks

The survey results highlighted that higher population of people are using surgical mask to protect their self from the COVID-19 virus. This surgical face masks (Fig. 1a) are made of non-woven fabric that has

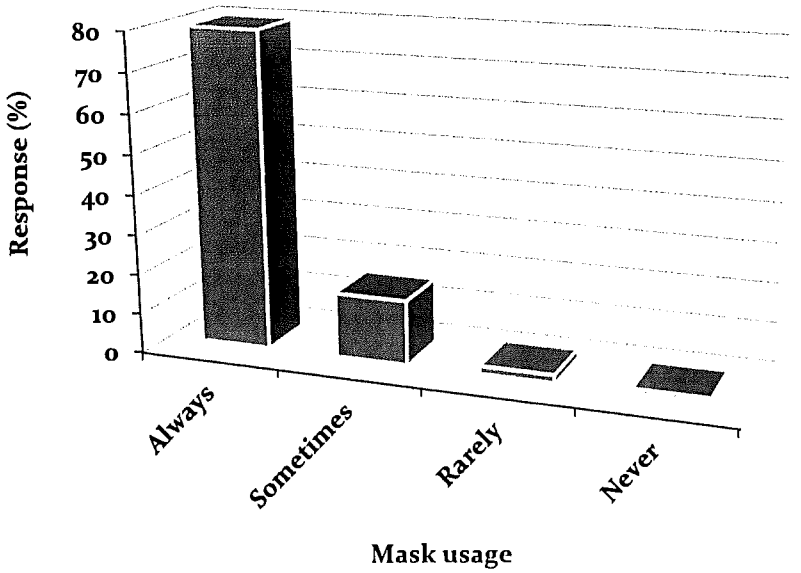

Fig. 4. Importance of mask usage.

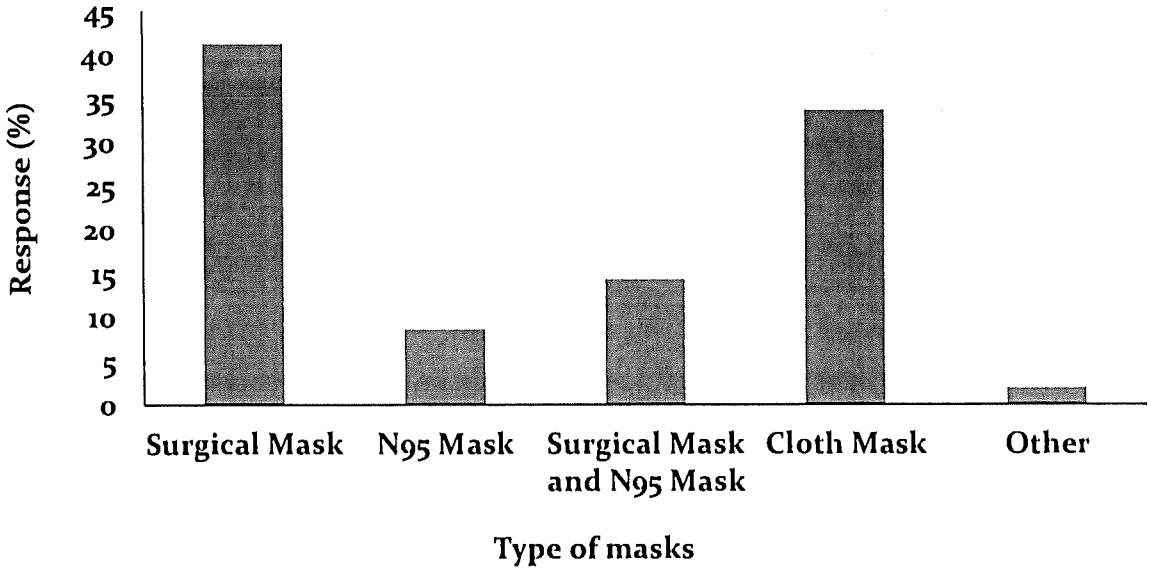

Fig. 5. Types of masks used by people.

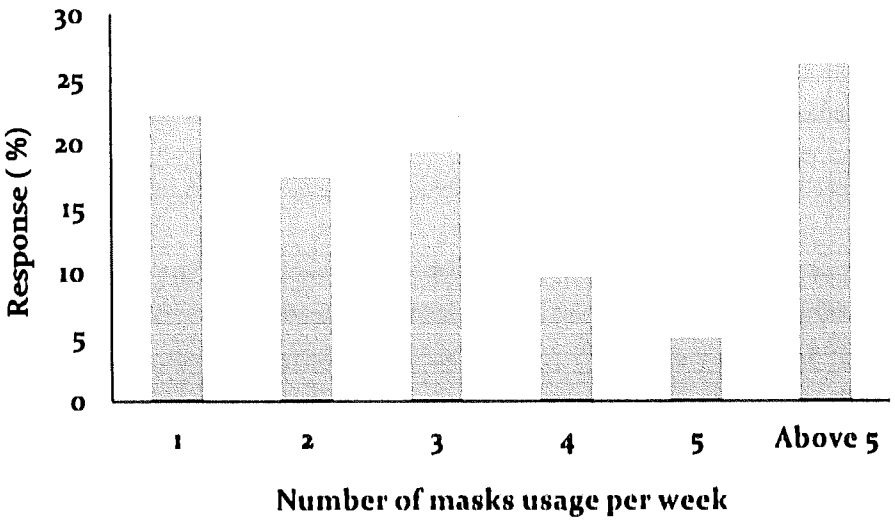

Fig. 6. Number of masks usage.

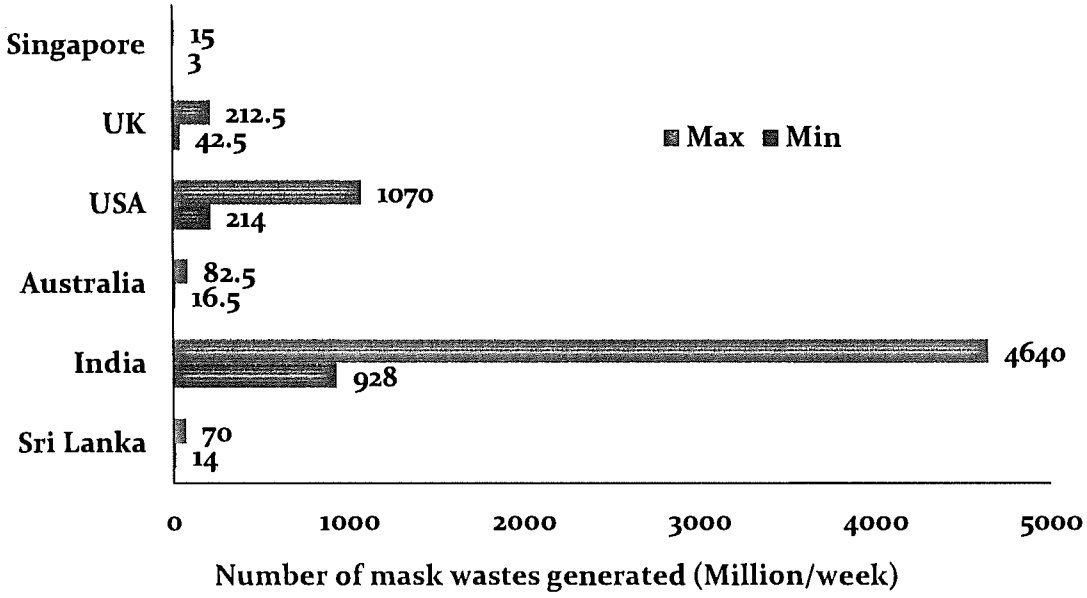

Fig. 7. Total amount of mask waste generated per week.

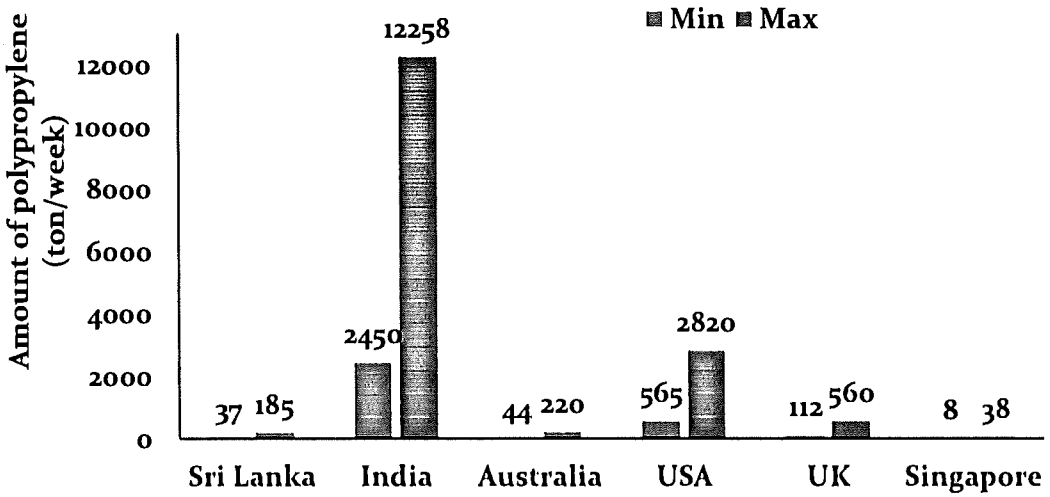

Fig. 8. Total amount of estimated polypropylene from face mask wastes per week.

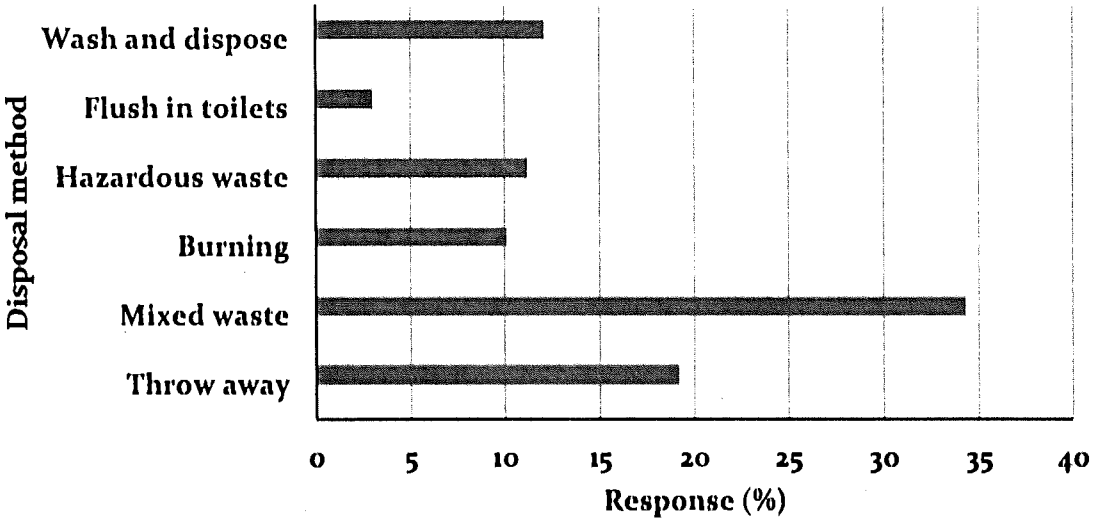

Fig. 9. Disposal method of mask waste.

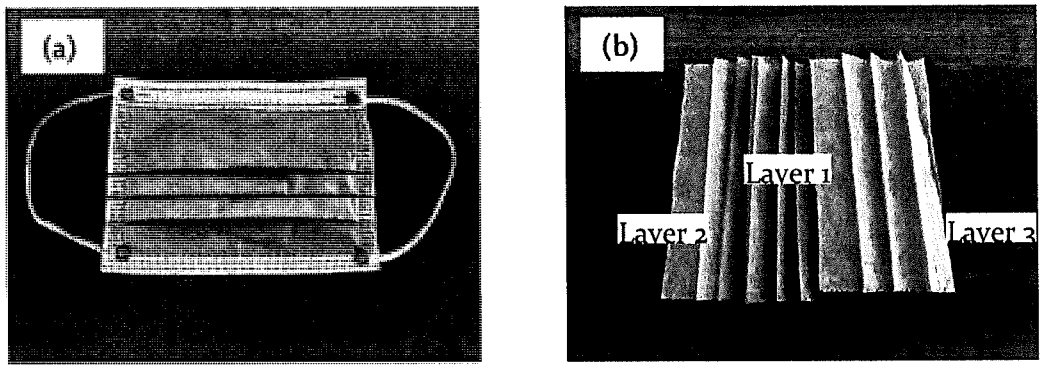

Fig. 10. Structure of surgical mask: (a) surgical mask (b) three layers in the surgical mask.

better filtration of bacteria and air permeability, while remaining less slippery than woven fabric. Based on the barrier properties and breathing resistance, the ASTM F2100 (ASTM, 2007) and EN ISO 15223-1 (BS EN ISO 15223-1, 2016) classified this mask into different types (i.e. low barrier, moderate barrier and high barrier) (Chellamani et al., 2020). This surgical mask mainly consists of three layers (Fig. 10b) such as outer hydrophobic non-woven layer (translucent), middle melt-blown layer (generally in white colour), and an inner soft absorbent non-woven layer (green, blue, or white colour). The polypropylene (i.e. known as plastic) is used as a major material to produce this surgical mask. However, other polymers like polystyrene, polycarbonate, polyethylene or polyester are also used to produce this mask (Akber et al., 2020).

The highly recommended mask to prevent the virous spreading is N95, which consists of four layers of material: an outer layer of spunbond polypropylene; a second layer of cellulose/polyester; a third layer of melt-blown polypropylene filter material; and an inner (fourth) layer of spun-bound polypropylene. The typical raw materials used to produce N95 mask is polypropylene similar as the surgical mask (Boyle et al., 2020). Further, the weight of the surgical and N95 face masks is 3.5 g and 18.14 g, respectively. The ear loops of both face masks were made of natural and synthetic polyisoprene (i.e. latex-free) rubber. While, the ear loops in the cloth mask was made by cloth. There are mostly two kinds of cloth masks, "commercial cloth masks" and "homemade cloth masks" (Santarsiero et al., 2020a; Santarsiero et al., 2020b). These cloth masks are made of multi layered of cloth like old t-shirts and sewing material (Ayse et al., 2020). Cloth mask are also made of cotton and nylon, which have water resistant property. Furthermore, the fabric of cloth mask comes under the non-medical mask category, whilst the surgical and N95 masks are known as the medical mask. The filtration performance of these cloth masks are depends on many variables, such as thread count, number of layers, fabric type, and resistance to water (Chughtai et al., 2020). The filtration efficiency of cloth mask is varying as some fabrics filter better than others. However, the filtration efficiency of cloth mask is lower than that of from medical mask.

4. Impact of mask waste on environment

The mask wastes are increased across the world as the people are not following the appropriate disposal methods for the used mask. Thus, it creates a new environmental challenge. Further, there are no appropriate mask or plastic waste collecting method specified in whole countries or part of the region in Sri Lanka, India, Pakistan and China (Sangkham, 2020). This is adding a vast amount of plastic and plastic particle waste in the environment, which may end up in the streets and landfills. Besides, it gets into the waterways and reach the fresh water and marine water. This adds the presence of the plastics into the aquatic medium. The health and environmental effects of plastic and plastic particles due to the inappropriate disposal of facemasks were also highlighted by number of literatures (de Sousa, 2020; Patrício Silva et al., 2021; Sangkham, 2020). Furthermore, the production of the face masks also contributes the emission of CO_2, which will potentially contribute to the global warming (Liebsch, 2020). The processes of propylene, small aluminum strips and polypropylene in the production of N95 and surgical mask contributes the significant amount of CO_2 emission to the environments. Furthermore, production of fabric, sewing and weaving process of cloth mask fabrication also contributes the CO_2 emission to the environments (Liebsch, 2020).

The N95 mask production release 50 g CO_2-eq per single mask, excluding the transportation process (Klemeš et al., 2020a). Surgical mask is embodied with 59 g CO_2-eq per single and the highest share is from the transportation process (Klemeš et al., 2020a). Whilst, the cloth mask production contributes about 60 g CO_2-eq greenhouse gas emission per single mask (Klemeš et al., 2020a). However, this would create a massive impact to the atmosphere because, millions of face masks are produced all over the world to control the pandemic situation. The face masks used by medical examiners in hospitals are carefully collected as its hazardous waste. A study was conducted in the UK and analyzed that if each individual uses one disposable surgical mask every day for a year, this would create over 124,000 tons of unrecyclable plastic waste 66,000 tons of contaminated waste and 57,000 tons of plastic packaging (Ayse et al., 2020). However, there is currently no specific waste stream for these products if it used by the public. Mostly, it is thrown recklessly in the streets or collected as a mixed waste.

In the handling of urban solid waste and hazardous medical waste, the pandemic has led to a significant challenge. The collected hospital face masks and other mixed waste are sent to the incineration and landfill. However, due to the existence of the plastics in the mask, such methodologies often have the potential to cause adverse environmental effects. Most plastics are chemically stable, resistant to corrosion and, difficult to degrade by microorganisms (Webb et al., 2013). Yet they prefer to remain in the soil and pose environmental threats. The solution that allows the chemical energy content of plastics to be recovered for useful purposes is the incineration of medical waste coupled with waste heat recovery. For medical waste incineration, the WHO has suggested 900 °C and 1200 °C to guarantee safe destruction, but most of them are unaware of the temperature range (Klemeš et al., 2020a). However, with heat recovery, there are limitations to the widespread use of incineration. Public worries about dioxin and furan trace emissions can become troublesome. The transportation of those waste to relevant disposal site also consume energy and release greenhouse gases to the environment. Recent study by Kumar et al. (2020) stated that 10 ton of PPE waste including face masks travelled 10 km for the relevant disposal site resulted in total global warming potential (GWP) impact of 2.76 kg CO_2-eq.

The mask littered in the soil can impact the fauna in which it causes entanglement and can cause death (Fig. 11). For instance, it is reported in Columbia that a bird was tangled in a discarded coronavirus facemask in a tree. Then died after the mask is wrapped around its body and beak (Boyle, 2020). Further, when the mask is mistaken for food by an

Fig. 11. Threat to birds due to usage of mask (Boyle, 2020).

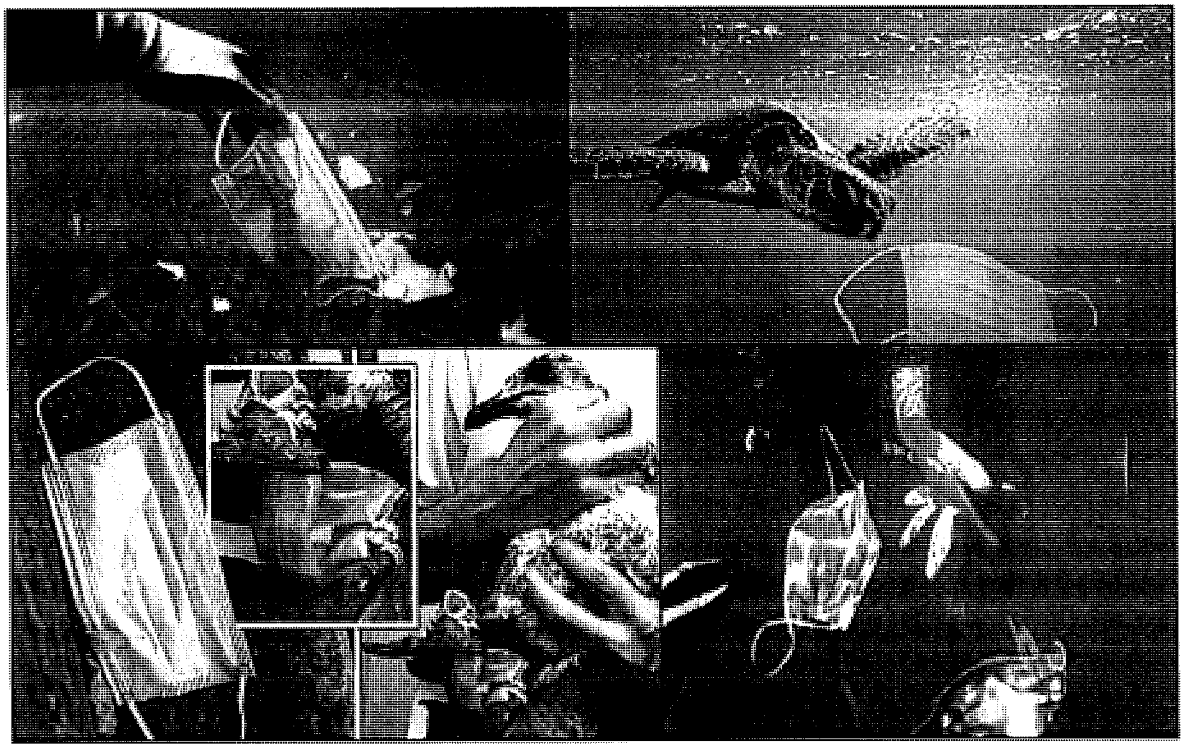

Fig. 12. Threats to aqua life due to usage of face masks ([illegible]).

animal, which is unfortunately a common occurrence, the plastic can fill stomachs, decrease food intake, cause animals to starve and die.

The mask wastes also conveyed into the rivers and enters the fresh water and sea water. This creates the plastic pollutions to the aquatic medium (Fig. 12). Marine plastic adsorbs toxins and organic contaminants, which ensures the pollutant particles bind as a toxic film to the surface of the plastic ([illegible], 2020). As a result, it is also possible to poison the marine animals, which ingest plastic. It may destroy them directly, or weaken them, rendering them more vulnerable to other threats ([illegible], 2020). Ingested plastic can interfere with impair reproduction, growth and development of young ([illegible] et al., 2020b; [illegible] et al., 2020). Further, it can also cause entanglement, which lead to death in aquatic fauna like birds and other under water animals. Fragmentation of the macro plastic in the mask could occur due to various abiotic factors such as photodegradation, weathering, corrosion, and aquatic immersion forming the secondary micro plastics ([illegible] et al., 2020). Hence, bio accumulation of such microplastic occurs in the major food web to human existence and cause accumulation of toxins. This causes not only detrimental environmental effects, but also economic and social effects as shown in Table 1.

5. Solutions to reduce the mask waste

Plastic is a significant continuing debate, which is not biodegradable material and induces further climate change pollution by affecting land and groundwater (Thompson et al., 2009). To overcome this issue, different management and assessment approaches have been used such as incineration and landfilling (Vanapalli et al., 2021). However, these are no longer preferred options to create the circular economy. Reduction of the plastic usage is completely not possible as it is an inevitable part of human behaviour, hence the search for another option to manage plastic waste is necessary. Therefore, governments are employing numerous international agreements to regulate plastic pollution. They include the Basel convention and its 2019 amendment, the United nations convention on the law of the sea, the international convention on the prevention of ship pollution, and the United nations global marine litter partnership (Patrício Silva et al., 2020).

Table 1
Environmental, economic and social impact of ocean plastic pollution in terms of sustainability.

Category	Issue	Consequences	Ref.
Environmental	• Microplastic enter food chains via ingestion. • Entanglement of the plastic waste. • Contain toxic chemicals as an additive. • Adsorb persistent organic pollutants (POP)s and heavy metals. • Occurrence of the plastic in the aquatic environment. • Improper disposal of facemask reaching water bodies. • Microplastics create a new microbial niche.	• Enter the major food web to human existence. • Bio accumulation of toxins. • Cause the suffering and death of charismatic marine animals (e.g. seabirds, turtles, and crustaceans). • Toxic chemicals of plastic can be released during the degradation processes (either chemically or biologically) in the open environment. • Bioaccumulation of the POP and heavy metal in aquatic organisms, eventually enter the food web. • Environmental deterioration and degradation up to climate change. Contribute to drought and global warming due to carbon emission. • Act as a medium for further outbreaking of COVID-19 since the particles tends to proliferate microbes and disseminate in the food chain and/or direct attacks. • Affect microbial habitual and the environmental processes in aquatic ecosystems.	(Haque et al., 2021; Klemeš et al., 2020b)
Social	• Pollution of aquatic environment or shore with plastics or plastic particles. • Ingesting and entanglement of the plastic.	• Reduces aesthetic and recreational value thus, impacts to human social and mental stability. • Images of plastic covered shorelines or charismatic megafauna entangled, or ingesting plastics are visually impactful.	(Stafford and Jones, 2019; Yang et al., 2020)
Economical	• Environmental and social impacts of plastic and plastic particles.	• The clean-up activities, lifesaving activities of the aquatic bodies are expensive. • Tourism industry experiences significant loss.	(Zhang et al., 2020)

Reusing and recycling are viable options for plastic waste management, but prior to that identification of the condition of the plastic is required and cleaning or repairing steps are necessary according to its source (Liang et al., 2021). The collected plastic wastes are shredded initially and sorted using the techniques like spectroscopy, X-ray fluorescence, flotation, magnetic or density separation. Then the optical sorter is used to differentiate the colour, and the separated plastics are melted and extruded into pellets for reuse. The recycled plastics are sold to local plastic manufacturing firms that can ultimately manufacture useful products such as engine oil, textile, footwears, and concrete additives. These process is financially not feasible as it is expensive, hence as an alternative way, the automated separation of various plastics could be adopted prior to the shredding (William Wan and Sadoo, 2020).

Furthermore, medical waste also contribute significantly to the global plastic waste (Huang and Huang, 2004). These wastes should be given a special consideration for disposal as it might be hazardous or radioactive. As a first step, the classification of hospital waste at its origin is done for the management of waste, which has the possibilities to avoid the spread of infection to the waste handlers. The waste is collected in separate bins or bags with a clear identification and then the waste containing bags must be disinfected and sealed with double-layered plastic bags (yellow color) prior to transportation from the origin. According to WHO, the biomedical waste includes 10% of infectious hazardous waste, and 5% of toxic or chemical waste (Ilyas et al., 2020). The commonly used disinfection techniques for the management of hospital wastes are pyrolysis technique and microwave technique. The temperature is sustained at around 540°C-830°C in high-temperature pyrolysis, which involves pyrolysis-oxidation, plasma pyrolysis, induction-based pyrolysis, and laser-based pyrolysis (Ilyas et al., 2020). This effectively offers advantages such as low emission rate, reduction of inert residual volume by up to 95% and reduction of mass by up to 90% (Ilyas et al., 2020). Another technique used for the medical waste is the medium microwave technique, which works within the temperature range of 177–540 °C. The key benefits of the microwave technique are comparatively lower energy and action temperature, limited heat loss, and less environmental burden without harmful residue during the disinfection phase (Haque et al., 2021).

There is a dramatic rise in the generation of plastic waste during the COVID-19 due to the increased use of face masks and change in customer preference to single use mask due to the hygienic problem (Patricio Silva et al., 2020). Therefore, many advanced waste management methods with minor variations in the general treatment of medical waste have been developed (Sangkham, 2020). Shortly after the first outbreak of COVID-19 in South Korea, 'Special Safe Waste Management Measures against COVID-19 was enforced on 28 January 2020 (Sangkham, 2020). COVID-19 waste cannot be kept for more than 24 h as per its guidelines and must be incinerated on the same day of collection. Therefore, most of the COVID-19 waste is sent for incineration at a temperature above 1100 °C (Sangkham, 2020). The microwave technique is often used in conjunction with autoclaving in the case of COVID-19 waste disinfection, where steam is used for sterilization (in the temperature range of 93–177 °C). The chemical disinfection technique is commonly used in combination with prior mechanical shredding for the pre-treatment of COVID-19 waste.

The polypropylene (i.e. plastic) used to produce the mask is according to the technical standards (Huang and Huang, 2004). Currently, this mask is discarded after the usage, as they are sensitive to heat and cannot tolerate high heat. However, due to the huge demand of the face masks caused by the COVID-19 crisis, the lifespan of the usage of face masks is investigated for the reuse (Chua et al., 2020). Reuse can be done using a strategy called mask rotation. In this strategy, rotation of the mask used each day can be carried out, allowing them to dry for long enough periods so that the virus is no longer viable (> 72 h) (CAGE's Webmaster, 2020). Proper storage for this technique requires either hanging the face masks to dry, or keeping them in a clean, breathable container like a paper bag between uses (Vanapalli et al., 2021; William Wan and Sadoo, 2020). Re-processing/decontamination is carried out by various methods like moist heat, dry heat, UV treatment, hydrogen peroxide(H_2O_2) vaporization. The H_2O_2, dry heat techniques have the opportunity for reprocessing of personal protectives (N95 face masks) and their re-use (Ilyas et al., 2020).

The recycling the mask by the appropriate processes is one of the alternatives used to reduce the plastic pollution generated by mask waste. Broadly, there are two ways for recycling such as primary recycling and secondary/chemical recycling. Primary recycling is the reusing of the product in their original structure. In the secondary recycling, the mask consisting of thermoplastic can be reused (Lechner, 2014). As they can be re-melted and re-processed into various end products; either to

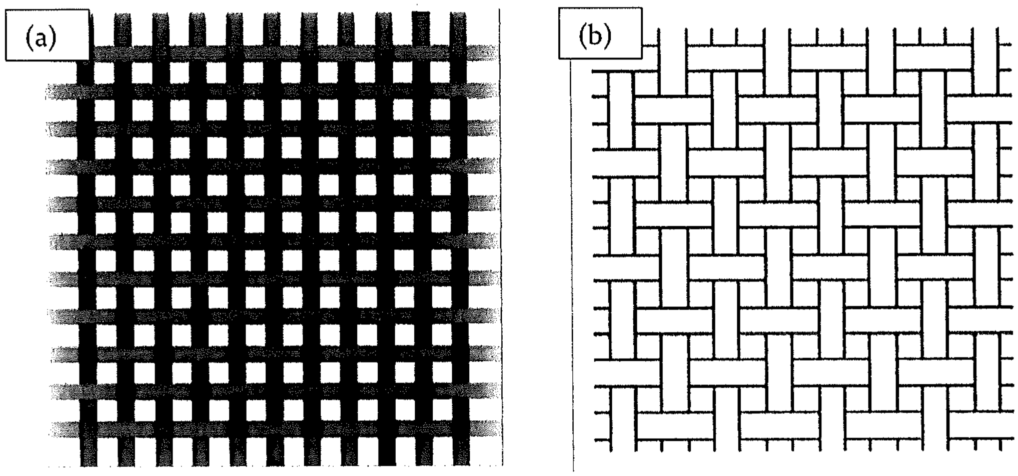

Fig. 13. Woven technology in: (a) surgical mask (Chellamani et al., 2020); and (b) plant fibre (Mannan et al., 2014).

produce the same product or composite products. Hence, this method can be employed to recycle the mask in a useful manner. However, considering the cost of a brand-new mask, this recycled mask is expensive for processing, also the filtering efficiency and the quality of the recycled mask is less than that of a new mask (China et al., 2020). Therefore, it is important to further examine for other alternatives to reduce the mask wastes.

Biodegradable mask is one of the modern sustainable alternative options to reduce the mask that induces plastic waste. The polypropylene in the mask can be replaced with other substitute organic and biodegradable materials with similar mechanical, physical and chemical properties such as light weight, high tensile strength, ecological safety, low cost and high biodegradable potential (Glukhikh et al., 2020; Samper et al., 2018; Saracusa and Blanco, 2020). The bioplastic and biodegradable polymers can be an option to replace the polypropylene. Bioplastic is a type of biodegradable plastic derived from biological substances rather than conventional plastic made of petroleum. The production of the mask using bioplastics must follow the standard requirements such as elasticity, water resistance and filtering properties. In general, due to the existence of polypropylene, all these properties can be found in bioplastics (Dinc et al., 2011). This biodegradable plastic reduces the CO_2 emissions by 30%-70% compared with the conventional one (Lackner, 2015). The biodegradable polymers can be obtained from different families like biomass production from agro resources such as polysaccharides (starches, lignocellulose), proteins, lipids and micro-organisms. Natural fibers such as cactus, banana, avocado, lotus, sisal, straw, hemp, maize bamboo, hemp, coffee and sugar cane have capability to meet the standard requirements to produce the mask (Fulan et al., 2020; Ramesh et al., 2017; Lam et al., 2016).

Furthermore, Fig. 13a shows the woven technology used in the filter of the surgical mask. Similar filters can be made with biodegradable plant fibers (Fig. 13b). Polysaccharides such as bamboo, hemp, coffee and sugar fibers are used to develop a bio mask and it prevents pollution caused by mask disposal and they can be processed and recycled (Ho, 2020; Lavi, 2020; Stall, 2020). Tea leaf waste also can be used to produce the filter part of the mask as it contains polypropylene and enhances the properties of poly lactic acid (PLA) in bioplastics (Lettaro and Taller, 2020). This indicates there is a possibility to use natural fibers waste and raw natural fibers to produce a cost-effective sustainable biodegradable green mask. Sugar cane waste mask (Lavi, 2020), Coffee-Based Face Masks (Ho, 2020) and Hemp Fiber mask (Stall, 2020) are currently available biodegradable mask. These types of biodegradable masks are manufactured with 99.99% dual antibacterial technology and have the high filtration capacity. Currently many research studies are going on developing the required specification for biodegradable mask to bring it to the standard of medical mask (Choi et al., 2021; Santarsiero et al., 2020a; Santarsiero et al., 2020b).

Although biodegradable face masks are made, individuals who are unaware of these benefits may not appear to alter their behavioral patterns from single-use plastics. Such masks are unpopular because they are only made in limited countries. Whilst the biodegradable face mask made from bioplastics claims to be degradable, there is still an uncertainty about the complete degradable nature of the biodegradable mask whereas a number of limitations still restrict it. For example, some plastics such as PLA require industrial scale composter to biodegrade (Vanapalli et al., 2021). Consequently, it is also mandatory and costly to build the appropriate infrastructure for biowaste management. Therefore, more investigations and research studies are needed, to assess the effectiveness and lifespan of sustainable biodegradable mask.

The use of recycled waste face masks as a composite material in various applications from all other alternatives to solve the global plastic crisis (i.e. mask pollution) would be a better approach in terms of circular economy. This is not only promotes the removal of collected waste from landfill sites, but also helps to reduce the production of waste in the first place. Substantially, it is restricting the use of natural resources and limiting the effects on the environment. A novel approach to reduce the plastic waste is convert this into construction materials. Different types of recycling methods such as mechanical recycling, chemical recycling and incineration have been used for the extraction of polypropylene from plastic wastes. In mechanical recycling, the polypropylene is separated from other forms of resin, washed to remove dirt and contaminants. Then grinded and compressed to minimize the particle size of the plastics, accompanied by heat extrusion and reprocessing into new plastic products. Chemical recycling allows plastic waste to be turned into initial monomers or another useful chemical (Ahmad et al., 2015; Canopoli et al., 2020; Maier et al., 2017; Poulakis and Papaspyrides, 1997; Rahimi and García, 2017).

The extraction of the pure polypropylene from the plastic waste containing various types of polymers could be achieved by pyrolysis method because it does not require pure plastics. The polypropylene pyrolysis was carried out using a two-stage continuous process equipped with auger and fluidized bed reactors linked in sequence (Park et al., 2020; Park et al., 2019). There have been different forms of reactors, such as stirred, screw kiln, circulating sphere, fluidized bed, spouted bed, plasma, and microwave-assisted reactors for pyrolysis (Park et al., 2019). It is stated that β-scission, end-chain β-scission, and intermolecular and intramolecular hydrogen transfer reactions are essential reaction mechanisms of pyrolysis (Park et al., 2020). A study by Ali et al., 2011 performed polypropylene pyrolysis blended with petroleum residue and coal to obtain a transportation fuel.

Most of propylene are developed by steam cracking of naphtha or low-molecular hydrocarbons (Park et al., 2020).

These extracted recycled polyethylene and polypropylene derivatives were used in road construction as a partial replacement for asphalt/bitumen (Williams-Wynn and Naidoo, 2020). There has been a great deal of research on the replacement of bitumen with plastics, use of plastics in asphalt-concrete mixtures (Appiah et al., 2017; Awoyera and Adesina, 2020; Bahij et al., 2020; Biswas et al., 2020; del Rey Castillo et al., 2020). A study by Hama and Hilal, 2017 concluded that the addition of fine, coarse, and mixed plastic wastes to self-consolidating concrete (SCC) enhanced its fresh properties, such as passing capability and filling capacity, at 12.5% replacement level of plastic by weight of fine aggregate. Furthermore, Khalid et al., 2018 investigated the performance of ring-shaped polyethylene terephthalate (PET) wastes in fibre-reinforced concrete beams. Their study showed that there was no significant impact on the failure mode of plastic fibers applied to concrete, but it improved the mechanical properties of the beams in terms of load at first crack and strength. A study by Arulrajah et al., 2017 also investigated the feasibility of using recycled plastic waste granules (i.e. linear low density polyethylene filled with calcium carbonate (LDCAL), high density polyethylene (HDPE) and low density polyethylene (LDPE)) blends with crushed brick and reclaimed asphalt pavement for road construction. Results showed that the introduction of plastic waste above 5% for road construction material, decreases the blends' stiffness, bearing capacity and robust module. However, the required performance was still achieved, and it has been concluded that the use of plastic waste as aggregate in asphalt improves the pavement's skid and crack resistance (Asi, 2007). A study by Kumi-Larbi et al. (2018) investigated the potential of using low-density polyethylene (LDPE) sheets plastic waste in sand blocks. Their study showed that strong and durable sand blocks can be produced without the need of water. Furthermore, recent study by Acu et al. (2018) used recycled plastic waste to make sustainable mortars with 75% of plastics as partial sand replacement to obtain M20 grade masonry mortar. The latest invention from mask waste has proved strongly that the face mask can be used for sustainable brick manufacturing (Adlakha, 2020). The sustainable brick was produced with 52% mask waste, 45% paper waste and 3% binder. This brick is alternative to the traditional masonry bricks, which have potential to reduce the plastic waste and cost.

Existing technologies used to extract the plastic derivatives from waste such as mechanical recycling, chemical recycling, incineration and pyrolysis have potential to separate the plastic particle in the mask wastes. The separated plastic derivatives from the mask have the potential to partially replace the cement and aggregates in the construction materials. This is strong, durable, waterproof, light weight, simple to mould and recyclable. Therefore, it can be used in the construction sectors. Further, it can be utilized as air and moisture barriers films and sheets used in insulating the building wraps, industrial adhesive tapes, plastic parts including pipes, masonry bricks. However, there is limited research available as it is a new waste. Therefore, more research needed to ensure the performance, efficiency and economic of construction materials or other products produced from this mask generated plastic wastes.

6. Summary and conclusions

This study analyses the number of different types of face masks usage in Australia, America, UK, Singapore, Sri Lanka, and India, through a public survey analysis. The study reveals that the number of face masks used during the COVID-19 pandemic. Results will help to understand the fundamental inside knowledge of mask waste generation and type of mask. These additional enhanced face masks containing plastic contributed to micro-plastic pollution in the aqua environment and also significantly impact the soil. A detailed study was therefore carried out to identify the difficulties of using more face masks and preventive measures. This paper highlighted the sustainable approach by integrating the use of natural plant fiber in the woven face mask technology to reduce the plastic waste induced by face masks. Further, upcycling this mask waste and producing construction materials such as artificial aggregates, light weight plastic block and production of ecological mortar can be a viable solution in the near future to reduce the plastic waste and environmental and health impact.

Contributor Roles Taxonomy (CRediT) author statement

K Selvaranjan: Formal analysis, Investigation, Resources, Data Curation, Writing - Original Draft, Review & Editing, Visualization; S Navaratnam: Conceptualization, Methodology, Formal analysis, Writing -Review & Editing, Visualization, Supervision; P Rajeev: Data Curation, Writing - Review & Editing; N Ravintherakumaran: Data Curation, Writing - Review & Editing.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this article.

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Exhibit #21

https://www.cnbc.com/2020/05/13/rash-irritation-downsides-face-masks-how-to-p

Do these 5 things to protect your skin from the downsides of face masks, doctors say

Published Wed, May 13 2020•12:39 PM EDT Updated Wed, May 13 2020•12:59 PM EDT Denise Mann, Contributor

Let's face it: We're going to be wearing cloth face masks for a while. Last month, the Centers for Disease Control and Prevention started recommending that people wear face masks in public places where social distancing is difficult to maintain.

While experts agree on the importance of wearing masks, as it can help slow the spread of Covid-19, there are downsides for some people, especially those who must keep them on during full workdays or anyone with underlying skin conditions (e.g., acne or rosacea).

Adam Friedman, a professor of dermatology a the George Washington University School of Medicine and Health Sciences, says he's seen an uptick in skin irritation — from inflammation with angry red rashes to tiny clusters of pimples around the nose and mouth — due to face coverings.

"When you blend together trapped breath, sweat and oil, you end up with a hot and moist environment under your mask. This often leads to greater risk of irritation," Friedman tells CNBC Make It.

Experts suggest doing these five things to keep your skin healthy, clean and

1. Choose soft, natural and breathable material

Once hard to find, cloth face masks can now be easily purchased from a variety of places online. But you shouldn't just buy just any "attractive-looking" mask, says
Noelani E. Gonzalez, a dermatologist and director of cosmetic dermatology at Mount Sinai West in New York.

"Choose a tight, secure fit with tightly woven fabric," she tells CNBC Make It. "You basically want something soft, natural and breathable — like 100% cotton. A maskmaking tutorial on the CDC's website also suggests using cotton (e.g., from sheets or a T-shirt).

"Avoid synthetic materials such as polyester, nylon and rayon," says Gonzalez. "These are more likely to make you sweat, which will dampen the fabric and, in turn, may cause irritation.

2. Pinpoint the cause of irritation

Often, rashes can be caused by something in or on your mask, as opposed to friction and trapped moisture.

"Some people may be allergic to adhesives, dyes or even the detergent they use to wash their cotton mask," says Gonzalez. If you start experiencing irritation, she advises consulting with your dermatologist before rushing to get some random, different kind of mask.

Can't immediately get in touch with your doctor? There are a few ways to do your own detective work in the meantime. "If the rash is on the tip of your nose, it might be because of the adhesive strip," according to Gonzales. (Some cloth masks have a strip on the inside to hold the mask in place.) If it's around your ears, it might be from the material of the ear straps.

Many detergents contain chemicals that can be harmful to the skin," she says. "So if the entire area covered by the mask on your face is irritated, it could likely be the soap you're using."

She recommends a "product for sensitive skin — without any dyes and scents, such as All Free Clear." It may also help to "run an extra rinse cycle to get rid of any detergent buildup."

3. Create a skin barrier with moisturizer

Putting moisturizer on your face throughout the day is the best way to decrease friction between the skin and mask.

"When your face is abraded by friction, the top layer of your skin releases water. As a result, your skin loses its natural moisture, while also becoming a less effective protective barrier against the mask," explains Friedman. "You'll start to see dry, cracked skin that then evolves into red inflammation."

He recommends applying an oil-free moisturizer about every two hours to dampen the skin. Creams from brands like CeraVe hydrate the skin well and provide skinbarrier replenishment. Non-comedogenic products are also great because they contain ingredients that won't clog pores or cause acne flare-ups, he says.

The advice is similar for hands, which often becomes dry over time from constant washing. According to Dawn Davis, a dermatologist with the Mayo Clinic, if your hands get severely dry and flaky, it's a good idea to pat them dry with linen or cotton (which is less abrasive than a paper towel) after washing.

If moisturizing with lotion alone doesn't work, she suggests adding on thick ointment, like petroleum jelly (many dermatologists recommend Aquaphor Healing Ointment). Then, cover each hand with a cotton sock overnight to lock in extra moisture.

4. Keep your skin clean

Less is more when it comes to cleansing your face, so avoid using any strong face soaps or exfoliators, when possible.

Friedman suggests sticking to gentle and simple formulas that are more calming to the skin. "Wash your face before and after wearing a face covering. Don't forget to apply moisturizer after washing."

If your dermatologist has you on any specific medication or face product, don't stop using them. "Continuing your regimen for acne, rosacea or any other skin condition will keep your skin as healthy as possible and protect against any exacerbation caused by face masks," he says.

Lastly, this is the time to pause your beauty routine and skip the foundation and concealer. "When you wear makeup under a mask, the increased humidity on your skin can lead to clogged pores and breakouts," Gonzales explains. "Not wearing makeup will help your skin breathe better."

5. Stay in touch with your dermatologist

We should all be keeping up with our dermatologist checkups, but it may be necessary to consult with your doctor more than once a year. (Many are now seeing patients virtually through video conferencing apps).

"If you develop an irritation and it doesn't get better after a few days of using an over-the-counter cortisone cream [to help with a rash or redness] and/or moisturizer, check in with your doctor to see what's going on," Gonzalez advises.

Denise Mann, M.S., is a consumer health researcher. Her work has been featured in HealthDay, Reader's Digest, MedicineNet, Everyday Health and the Dallas Morning News, among many others.

Exhibit #22

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The elevation training mask induces modest hypoxaemia but does not affect heart rate variability during cycling in healthy adults

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ABSTRACT: This study examined the acute effects of the elevation training mask (ETM) on haemodynamics and heart rate variability (HRV) at rest, during cycling, and during recovery in healthy adults. Fifteen healthy male (N=9) and female (N=6) adults (27.0 ± 1.14 years) completed two trials with the mask (MASK) and without the mask (CON). The 40-minute cycling exercise protocol included 10-minute phases of (1) rest, (2) 50% of VO_{2peak} cycling, (3) 70% of VO_{2peak} cycling, and (4) recovery. Blood pressure and pulse oximetry saturation (S_pO_2) were measured at each phase. An Actiwave-Cardio ECG monitor (CamNtech, UK) was used to measure HRV variables including time and frequency domains. A greater response in systolic blood pressure (p=.035) was observed at rest while S_pO_2 (p=.033) was lower during high-intensity cycling (70% of VO_{2peak}) in the MASK trial. The HRV indices were not different between trials during cycling. However, heart rate (p=.047) was greater while inter-beat interval and sympathovagal balance (the ratio between low-frequency and high-frequency components; ln LF/HF, p=.01) were lower in the MASK than the CON trials during recovery. Wearing an ETM during high-intensity cycling (70% of VO_{2peak}) induces modest hypoxaemia. Although this device did not affect HRV changes during cycling, it seems to delay the cardiac-autonomic recovery from exercise. Healthy adults may be required to perform high-intensity exercise with an ETM to simulate a hypoxic environment, but future studies are needed to determine whether repeated exposure to this condition provides similar benefits as altitude training.

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Key words:
Heart rate variability
Elevation training mask
Exercise
Haemodynamics

INTRODUCTION

Inspiratory muscle weakness is associated with slow oxygen uptake kinetic, lower limb muscle weakness, and exercise intolerance [1]. It has also been identified as a limiting factor for exercise performance in patients and sedentary individuals [2,3]. Respiratory muscle training (RMT) has been introduced as a clinical approach for those with chronic heart failure or cardiopulmonary disease, as well as the elderly, to improve their inspiratory muscle strength, exercise tolerance, and quality of life [4,5]. RMT is designed to reduce perceived breath effort and breath work, which results in the delay of respiratory muscle fatigue and attenuation of the respiratory muscle metaboreflex [6]. RMT is known to provide health benefits for haemodynamic and autonomic regulation, which may result in decreasing resting sympathetic activity in addition to baroreceptor sensitivity and sympathovagal balance improvements [7].

Traditionally, RMT is performed at rest and mainly applied to patients for improvements in disease outcomes or quality of life [4,5], but in recent years exercise scientists have begun to consider the role of RMT during exercise and its value in providing a synergetic benefit with improvements in health and performance. The Elevation training mask (ETM 2.0, Training Mask LLC, Cadillac, Michigan, USA) was introduced in the commercial fitness market and is purportedly designed for the simulation of altitude training. The adjustable resistance cap provides different inspiratory resistance loads that are claimed as "altitude resistance" which ranges from 914 m to 5,486 m. A previous study reported that additional RMT training (2 times/week) combined with conventional training improved rowing performance in female competitive rowers, both in a 6 min all-out and a 5,000 m trial [8]. Even though RTM combined with training

showed performance improvement, the different equipment (i.e., manufacture or model) may have caused different outcomes in performance improvement. Recently, two studies that utilized the ETM 2.0 device during high-intensity cycling exercise or physical training did not show aerobic performance improvement in healthy adults and Reserve Officers' Training Corps (ROTC) cadets, respectively [9,10]. Although many athletes in American football, various types of martial arts, and CrossFit use this equipment during high-intensity aerobic or resistance training, it is still unclear whether this equipment truly provides synergetic benefits for health and performance.

In this context, we believe that understanding about the physiological responses to wearing an ETM during exercise is important not only to assess its potential as a prospective ergogenic aid, but also to design ETM-utilizing exercise protocols. Heart rate variability (HRV) assessments would provide information on how cardiac autoregulation is altered by wearing the ETM at rest, during exercise, and recovery because HRV indices reflect the extrinsic regulation of heart rate that involves sympathetic, para-sympathetic activities, and sympathovagal balance [11]. Therefore, the purpose of this study was to examine the acute effects of the ETM on haemodynamics and HRV at rest, during cycling, and recovery. It was hypothesized that the ETM would show significant differences in blood pressure, oxygen saturation level (S_PO_2), and HRV responses compared to a control trial without the ETM.

MATERIALS AND METHODS

Subjects

Initially, 20 healthy male and female adults enrolled in this study. All participants were recruited by advertisements such as flyers and oral presentations in the university. Inclusion criteria of this study are as follows: 1) participants who were aged 20-40 years, 2) able to participate in cycling exercise, and 3) body fat percentage under 30%. If participants fell outside these parameters and/or had cardiopulmonary-related diseases, they were excluded. This study was approved by the university's Institutional Review Board (IRB) and all participants received information of the study procedure, benefits, and risks of the experiment before providing written consent. During the study period, five participants dropped out for personal reasons. Therefore, 15 participants (male, n=9, female, n=6) completed this study. Participants' basic characteristics are presented in Table 1.

Study Design

This study was conducted in a randomized and crossover design. Participants reported to the human performance laboratory three times during the study period. In the first visit, participants' height, body weight, body fat percentage, respiratory function, and VO_{2peak} were measured to assess basic characteristics. In the second and third visits, participants randomly completed two trials of cycling exercise protocols with or without an ETM. Forty minutes of the cycling exercise protocol was divided into 10 minutes of 1) resting, 2) 50% of VO_{2peak} cycling, 3) 70% of VO_{2peak} cycling, and 4) recovery, with a seven-day interval between trials. During this seven-day interval, participants were asked to carry on their normal activities and not to change any exercise habits. Heart rate, blood pressure, S_PO_2, heart rate variability, self-perceived fatigue and self-perceived breath efforts were measured at each phase. The study procedure is shown in Figure 1.

Methodology

Height, body weight, and body fat percentage. Height and body weight were measured to the nearest 0.1 cm and 0.1 kg, respectively,

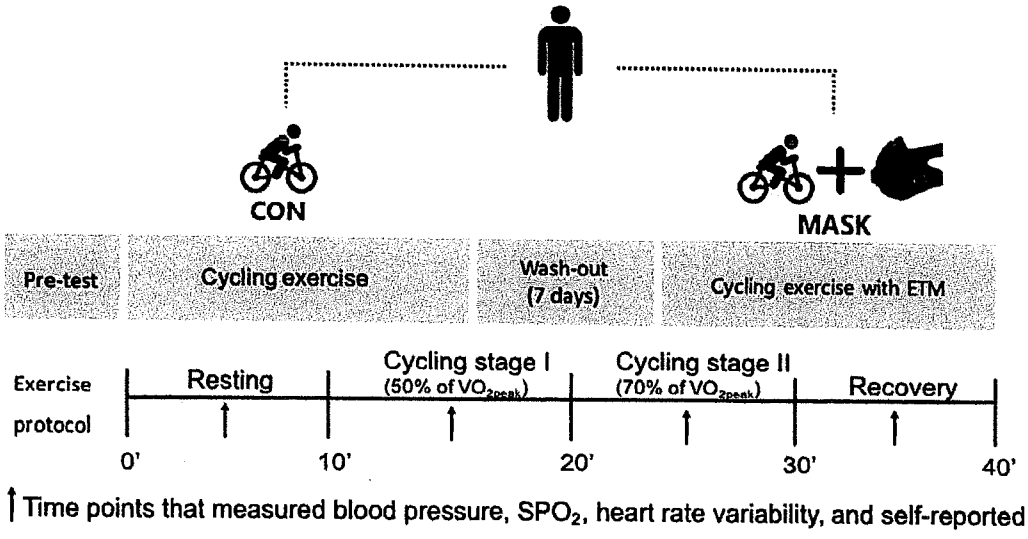


TABLE 1. Basic characteristics of participants (mean ± s).

Variables	Total (N=15)	Male (N=9)	Female (N=6)
Age (years)	27.0 ± 1.14	28.1 ± 1.52	25.3 ± 1.63
Height (cm)	171.3 ± 2.60	176.4 ± 3.02	163.6 ± 2.46
Weight (kg)	72.7 ± 4.04	80.1 ± 4.90	61.6 ± 3.96
Body fat percentage (%)	16.4 ± 2.40	11.7 ± 2.00	24.7 ± 1.71
Systolic BP (mmHg)	118.1 ± 3.28	125.4 ± 2.69	107.0 ± 4.16
Diastolic BP (mmHg)	70.3 ± 1.86	72.9 ± 2.13	66.3 ± 2.86
FVC (%)	91.0 ± 2.26	91.6 ± 3.07	90.2 ± 2.26
FEV1/FVC ratio	0.9 ± 0.02	0.9 ± 0.02	0.9 ± 0.04
VO_{2peak} (ml/kg/min)	34.1 ± 1.29	36.1 ± 1.64	31.1 ± 1.50

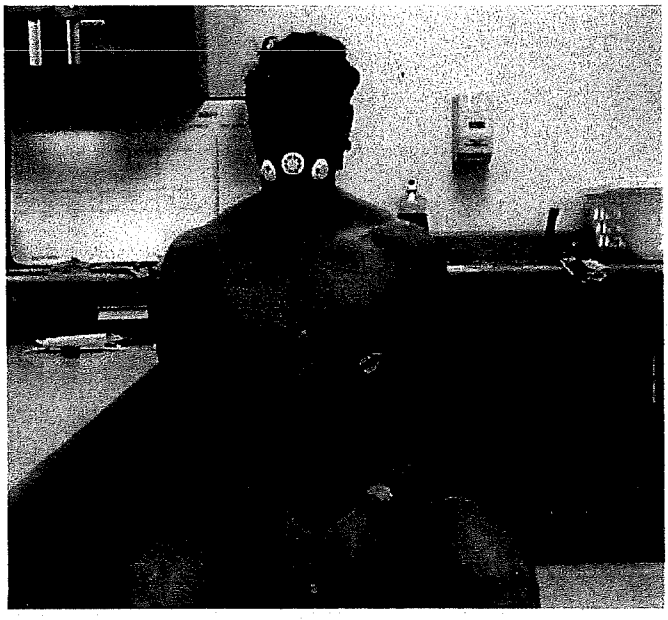
BP; blood pressure, FVC; forced expiratory volume in one second, FVC/FEV1; forced vital capacity/forced expiratory volume in one-second ratio.

with a stadiometer (PAT #290237, Novel Products, Rockton, USA) and a digital scale (HD-366, Tanita, Tokyo, Japan). Three sites of skinfold thickness were measured by one trained researcher using Lange skinfold calipers (Beta technology, Santa Cruz, CA, USA) to estimate body fat percentage. The three sites of males were chest, abdominal, and thigh, while for females they were triceps, suprailiac, and thigh. Each site was measured three times at the right side of the body, and the average score was recorded. Body density was calculated using the Jackson Pollock method [12] and body fat percentage was estimated by the Siri equation [13].

Respiratory function. The respiratory function test was measured using an electronic spirometer (MicroLab, CareFusion, USA). The test is purportedly performed to examine respiratory diseases such as asthma and chronic obstructive pulmonary disease (COPD). If any subjects had symptoms of airflow obstruction (i.e., ratio of forced expiratory volume in one second (FEV_1) / forced vital capacity (FVC) < 0.7, FEV_1 % predicted < 80%), they were excluded from the study [14]. Participants first sat in a chair for 5 minutes before they started the test. After 5 minutes, participants put on a nose clip and a spirometer mouthpiece. The respiratory function test consists of 1) three normal breaths, 2) a maximal deep inhalation followed by a 3) forceful exhalation, and 4) three more normal breaths. All participants were tested three times, and the highest scores of FEV_1 and FEV_1/FVC were recorded.

Blood pressure and S_PO_2. Blood pressure and S_PO_2 were measured once at rest, during cycling (50% and 70% of VO_{2peak}), and during recovery. Blood pressure was measured with a mercurial sphygmomanometer (BMS 12-525, Graham Field Inc., USA) by a trained technician, and S_PO_2 was measured with a pulse oximetry saturation analyzer (Checkmate, Israel). The values were recorded as mmHg and percentages, respectively.

Peak oxygen uptake test. Participants performed a VO_{2peak} test a True-One 2400 metabolic cart (ParvoMedics, East Sandy, Utah, USA) to accurately prescribe exercise intensities for the cycling exercise. Participants performed cycling with an initial work rate equal to 60 W (1 kp) and a pedalling rate of 60 revolutions per minute (RPM) for 2 minutes. Thereafter, the work rate increased by 30 W (0.5 kp) every 2 minutes until the participant reached exhaustion. VO_{2peak} was determined when participants met at least 2 of the following conditions; (a) inability to keep up the pedalling rate of 60 rpm for more than 5 seconds with verbal encouragement, (b) respiratory exchange ratio (RER) 1.10, (c) rating of perceived exertion (RPE) ≧19 (Borg 6–20 scale), or (d) volitional fatigue.



Heart rate variability. Participants were instructed not to drink any caffeine-containing products for at least 24-48 hours before any of the tests. An Acti-Cardio monitor (CamNtech, UK), which traces the electro cardiograph (ECG), measured the HRV variables using two electrodes adhering to the participant's upper chest (5th intercostal space and 10 cm away on the left side near lead fours and five) (Figure 2) [15,16]. Sample rate and resolution were set at 1,024 Hz and 10-bit. Participants' ECGs were recorded for 40 continuous minutes for all phases of the test. For HRV analysis, a 5-minute period of each phase free of noise was selected according to the task force criteria of the European Society of Cardiology [17] and data were analyzed using the Activewave-Cardio Analysis software program (version 3.0.8, CamNtech, UK). The HRV variables reported with time included average heart rate, inter-beat interval (IBI), standard deviation of the IBI interval (IBISD), and root mean squared successive difference (RMSSD). Those reported with frequency domains included low-frequency (LF) and high-frequency (HF) components, and the ratio between LF and HF components (LF/HF ratio).

Self-perceived fatigues and breath effort. To measure perceived muscle fatigue and breath effort, subjects' subjective feelings were evaluated at the end of each phase using Borg's 6-20 rating of perceived exertion scale (RPE) for overall fatigue and a modified scale (range from 0 to 10) for the rate of perceived breath effort (RPBE). The number '0' indicates that the participant perceived no breathing effort at all while '10' indicates the maximal effort of breathing.

Cycling exercise. Prior to cycling exercise, participants sat quietly on a chair for 10 min as a rest phase, then performed the cycling exercise (Monark 894E, Sweden) for 20 min at two different intensities: 50% of VO_{2peak} for the first 10 min and 70% of VO_{2peak} for the next 10 min. The average loads of 50% and 70% VO_{2peak} were 1.4 ± 0.37 kp and 2.1 ± 0.55 kp, respectively. Participants maintained a pedalling rate of 60 RPM during cycling. After completion of cycling, participants sat on the chair for 10 min as a recovery phase.

Elevation training mask. The elevation training mask (ETM 2.0, Training Mask LLC, Cadillac, Michigan, USA) is a device on the commercial fitness market that claims to improve athletic performance by simulating training at altitude via restricting airflow. The ETM covers the nose and mouth with a neoprene band and flux valves that adjust the resistance of the respiration. There are four different types of plastic resistance caps (i.e., 8, 4, 2, and 1-hole open caps) with the smaller air hole caps in the flux valves causing increased resistance, making it more difficult to breathe while wearing the mask and thereby simulating higher altitude. In the current study, the ETM mask was adjusted to simulate an altitude resistance of 1,829 m.

Statistical analysis

Statistical analyses were performed with SPSS software version 25.0 (SPSS Inc. Chicago, IL, USA). All data are expressed as means and standard errors. The Kolmogorov-Smirnov test was used to analyze the normal distributions of dependent variables. If any dependent variables were not normally distributed, a natural logarithmic transformation was performed to meet the assumptions of parametric statistical analysis. 2 (trial) x 4 (time) factorial analysis of variances (ANOVAs) for repeated measures were used to assess the effects of wearing an ETM on blood pressure, S_PO_2, heart rate variability, and self-perceived fatigue and breath effort. If any significant interaction or main effects were detected, Tukey's HSD post-hoc test was applied. Effect sizes were reported as partial eta-squared (η^2_p) indicating a small effect =.01, medium effect =.06, large effect =.14 [18]. The significance level was set at.05 for all tests.

RESULTS

Changes in haemodynamics

The changes of blood pressure and S_PO_2 are presented in Table 2. There were no significant interaction effects for group by time on blood pressure, $p > .05$. However, the systolic BP was greater in the MASK than the CON trial at rest ($p=.035$, $\eta^2_p=.279$). Regarding

TABLE 2. Changes in blood pressure and S_PO_2 at rest, during cycling, and recovery (mean ± s).

		Rest	50% Cycling	70% Cycling	Recovery	F-value [η^2_p]		
						Group	Time	G x T
Systolic BP (mmHg)	CON	110.1 (2.15)	130.3 (5.87)	147.1 (8.47)	114.5 (3.10)	5.43* [.279]	45.92* [.766]	0.89 [.060]
	MASK	114.5+ (3.42)	136.0 (5.95)	160.4 (7.91)	118.5 (2.43)			
Diastolic BP (mmHg)	CON	68.4 (1.94)	72.0 (3.26)	71.0 (3.09)	67.9 (2.68)	0.12 [.009]	1.32 [.086]	0.15 [.011]
	MASK	69.6 (1.98)	73.1 (3.02)	72.5 (3.11)	68.7 (2.40)			
S_PO_2 (%)	CON	97.7 (.21)	97.3 (.18)	97.0 (.14)	97.3 (.25)	7.98* [.363]	11.96* [.461]	3.74* [.211]
	MASK	97.9 (.19)	96.9 (.19)	96.1+ (.17)	97.0 (.17)			

BP; blood pressure, G x T; group x time; +p<.05, significant different between the groups; *p<.05, significant main or interaction

S_PO_2, there was a significant interaction effect for group by time ($p=.033$, $\eta^2_p=.211$). S_PO_2 level was significantly lower in the MASK than the CON trial during high-intensity cycling (70% of VO_{2peak}).

Changes in heart rate variability

Table 3 presents the changes of HRV indices with time and frequency domains. The HRV indices were not significantly different between trials at rest and during cycling. However, heart rate ($p=.047$, $\eta^2_p=.253$.) was significantly greater while IBI ($p=.05$, $\eta^2_p=.233$) was lower in the MASK than the CON trial during recovery. Regarding frequency domains, the lnLF/HF ratio was significantly lower in the MASK than the CON trial during recovery ($p=.01$, $\eta^2_p=.373$). However, no significant interaction or group effects were observed in lnLF and lnHF. The HRV indices including time and frequency domains were significantly changed across time in both trials ($p<.001$).

Changes in self-perceived fatigue and breath effort

There were no significant interaction effects for group by time on RPE and RPBE during the study. RPE ($F=24.43$, $p<.001$, $\eta^2_p=.636$) and RPBE ($F=70.83$, $p<.001$, $\eta^2_p=.835$) increased significantly as cycling intensity increased in both trials, but the RPBE was greater in the MASK than the CON trial across time ($F=40.18$, $p<.001$, $\eta^2_p=.742$).

DISCUSSION

Elevation training masks have been widely used in the athletic and recreational communities. Although the company claims that the increase in respiratory load, known as 'altitude resistance', improves respiratory muscle weakness and aerobic performance, it is unknown how cardiovascular function is altered in response to wearing an ETM during exercise and recovery. This study examined the acute effect of wearing the ETM on haemodynamics and HRV at rest, during cycling, and during recovery in healthy adults. The main findings of the study were as follows; 1) a greater response in systolic BP was observed at rest while S_PO_2 was lower during high-intensity cycling (70% of VO_{2peak}) in the MASK trial compared to the CON trial, 2) the HRV indices were not different between trials during cycling, but heart rate was greater and IBI was lower in the MASK than the CON trials during recovery, 3) sympathovagal balance (lnLF/HF ratio) was lower in the MASK than the CON trial during recovery, and 4) perceived breath effort was greater in the MASK than the CON trial across all time points.

Haemodynamic changes

In the present study, a greater response in systolic BP was observed at rest while S_PO_2 was lower during high-intensity cycling (70% of VO_{2peak}) in the MASK than the CON trials. Cardiovascular functions are interactively adjusted in response to respiratory function changes, such as breath frequency. The increase in respiratory load reduces the breath frequency rate, and this change influences the kinetics of oxygen consumption and CO_2 expiration [19]. It is commonly accepted that acute exposure at high altitude (>3,000 m) immediately increases the ventilation and decreases the arterial partial pressure of oxygen due to the low partial pressure of oxygen [20].

TABLE 3. Changes in HRV indices with time and frequency domains at rest, during cycling, and recovery (mean ± s).

			Rest	50% Cycling	70% Cycling	Recovery	F-value [η^2_p]		
							G	T	G x T
Time domain	Heart rate (beat/min)	CON	74.5 (3.34)	129.3 (5.89)	157.4 (4.61)	99.5 (4.25)	4.86* [.253]	332.42* [.964]	1.04 [.030]
		MASK	78.4 (2.20)	131.7 (4.49)	164.0 (4.53)	106.7+ (3.61)			
	IBI (sec)	CON	.826 (.035)	.477 (.021)	.384 (.012)	.610 (.023)	3.97* [.233]	299.28* [.958]	1.01 [.103]
		MASK	.773 (.021)	.462 (.016)	.370 (.010)	.570+ (.017)			
	IBISD (sec)	CON	.082 (.009)	.022 (.002)	.012 (.002)	.089 (.043)	.56 [.038]	9.61* [.407]	1.20 [.079]
		MASK	.088 (.006)	.024 (.006)	.009 (.001)	.040 (.005)			
	RMSSD (sec)	CON	.07 (.011)	.02 (.004)	.01 (.002)	.03 (.007)	.26 [.018]	35.53* [.717]	1.02 [.068]
		MASK	.10 (.041)	.01 (.003)	.01 (.002)	.03 (.006)			
Frequency domain	lnLF	CON	6.4 (.33)	3.0 (.39)	0.8 (.33)	4.9 (.27)	.02 [.001]	120.66* [.896]	3.10 [.181]
		MASK	6.9 (.22)	2.6 (.34)	0.2 (.38)	5.3 (.32)			
	lnHF	CON	5.4 (.39)	1.6 (.44)	0.01 (.42)	2.9 (.44)	2.84 [.169]	83.25* [.856]	2.48 [.150]
		MASK	6.1 (.20)	2.3 (.47)	-0.4 (.47)	4.2 (.36)			
	lnLF/HF	CON	1.2 (.07)	1.9 (.41)	0.7 (.78)	2.2 (.29)	8.34* [.373]	5.53* [.283]	1.55 [.100]
		MASK	1.1 (.03)	1.1 (.41)	-0.5 (.26)	1.3+ (.09)			

G; group, T; time, G x T; group x time, IBI; inter beat interval, IBISD; standard deviation of the IBI, RMSSD; root mean squared successive difference, lnLF; natural logarithm of low frequency, lnHF; natural logarithm of high frequency; +$p<.05$, significant different

In contrast to altitude exposure, Grandos and colleagues reported that an increase in respiratory load during steady state exercise did not increase the ventilation rate, but increased respiratory load may change metabolic CO_2 in the respiratory tract without significant changes in oxygen consumption kinetics [19]. The author assumed that the increased respiratory load might influence the ventilatory equivalents, leading to a decrease of the peripheral oxygen saturation level during exercise. The present study also found a similar result, as a greater decrease in O_2 saturation level was found in the MASK trial than the CON trial during cycling, but the difference was only observed during high-intensity (70% of VO_{2peak}) cycling. The differences between the present and previous studies may be associated with various factors such as different altitude resistance (1860 m vs 2743 m, 4572 m), subjects (both male and female vs male alone), exercise type (cycling vs treadmill), and intensity (50% and 70% vs 60% of VO_{2peak}). Additionally, it was assumed that respiratory function may not be a limiting factor for peripheral oxygen carrying capacity at rest or during moderate-intensity cycling in healthy adults despite the loaded respiration. However, the increased respiratory load during high-intensity cycling may be less sufficient for the kinetics of oxygen consumption to meet the exercise demands in working muscle (i.e., metabolic demands); thus it can be postulated that wearing an ETM during high-intensity cycling induces modest arterial hypoxaemia in healthy adults. Despite the ETM inducing modest arterial hypoxaemia, it is difficult to confirm that this device could provide similar beneficial effects of altitude training on haematological changes such as increased red blood cell and erythropoietin concentrations. A previous study reported that exposure to hypoxic conditions with an ETM for 60 minutes per week for 6 weeks was not sufficient to change the haematological variables [9]. Another study also revealed that 6 weeks of physical training with an ETM did not improve aerobic capacity in ROTC cadets [10].

Heart rate variability

The present study hypothesized that wearing an ETM during cycling would greatly influence HRV compared to not wearing an ETM. Although the HRV indices were not different between the trials at rest and during cycling, the heart rate was greater while the IBI was lower in the MASK than the CON trial during recovery. It has been demonstrated that respiration plays an important role in modulating HRV as well as the baroreflex [21]. The increase in respiratory resistance changes the inspiration process from passive to active, which results in recruiting an additional respiratory muscle group (i.e., sternocleidomastoid) [22]. Along with the additional muscle recruitment, slow oxygen consumption kinetics with loaded respiration may change the signalling in the central cardiovascular centre, which results in increasing heart rate and blood pressure. Another explanation may involve the intensive activation of the diaphragm metaboreflex, which can lead to increased sympathetic activity [23]. In agree- maximal inspiratory pressure increased HR and blood pressure in healthy males [24].

Regarding frequency domains, the lnLF and lnHF powers decreased as cycling intensity increased in both trials, but the variables were not different between the MASK and CON trials in the present study. Traditionally, LF power represents both sympathetic and parasympathetic modulation while HF power indicates parasympathetic activity [11]. It has been demonstrated that autonomic transition occurred toward sympathetic dominance when shifting from rest to exercise, such as cycling [25]. Previous studies also reported that frequency domains including LF and HF powers decreased as exercise intensity increased until the heart rate reached 120 to 180 beat/min [25,26], and this change continued until the first ventilation threshold [27]. Moreno's study also supports our result that frequency domains of HRV (i.e., LF, HF) are reduced while HR increases during moderate-intensity exercise (60% of VO_{2peak}) [28]. However, while the lnLF/HF ratio increased from rest (1.2) to moderate-intensity cycling (1.9) in the CON trial, this score did not change in the MASK trial (1.1 at rest and moderate-intensity cycling) in this study. It was believed that the sympathetic dominance during moderate-intensity exercise caused the increase in LF/HF ratio (sympathovagal balance) due to HF power withdrawal concomitant with increased LF power [29]. As respiratory variation is a primary factor for vagal modulation, it was assumed that an ETM-induced longer respiration phase might not diminish the vagal activity. After cycling exercise, lnLF/HF ratio was lower in the MASK than the CON trial in this study and this particular finding may be due to the restoration of the HF power from the cycling exercise. Although there was no significant difference in lnHF power between the trials during recovery, the mean lnHF power was greater in the MASK than the CON trial (4.2 vs 2.9), whereas the mean lnLF power showed similar values (5.3 vs 4.9). Nevertheless, it is premature to definitively conclude that our result is directly related to parasympathetic predominance, but perhaps it is because other physiological variables, including heart rate and IBI, were greater in the MASK than the CON trial despite the lower sympathovagal balance during recovery. We carefully assumed that even though extrinsic controls of heart rate (i.e., sympathetic and parasympathetic control) are changed by the ETM, the intrinsic controls of heart rate such as SA node might increase to compensate the changed autonomic regulations to remove the metabolic by-products after exercise. The present study confirms that wearing an ETM delays the cardiac-autonomic recovery from cycling exercise.

Perceived fatigue and breath effort

Rate of perceived exertion is a practical method to measure fatigue rate during exercise. In the present study, perceived fatigue did not differ between trials, but perceived breath effort was greater in the MASK than the CON trials across time. It was assumed that increased respiratory load decreased ventilation, and decreased ventilation

is supported by a previous study which found that perceived breath effort is positively associated with ventilation [30].

Limitations

Some limitations should be considered in this study. First, breath frequency rate was not measured in the present study. Even though previous studies demonstrated that the increase in respiratory load reduced the breath frequency rate [19], the absence of breath frequency rate measurement may limit explanation of the association between breath frequency rate and HRV in this study. Secondly, this study only tested in one condition with altitude of resistance of 1,829 m, even though the company introduces various altitude resistance conditions (914 m to 5,486 m). Therefore, applying different altitude resistances during exercise may result in different outcomes.

CONCLUSIONS

Our findings suggest that wearing an ETM (altitude resistance, 1,829 m) during high-intensity cycling (70% of VO_{2peak}) induces modest hypoxaemia. Although this device does not affect HRV changes during cycling, it seems to delay the cardiac-autonomic recovery from exercise. Based on this study, healthy adults may be able to follow an ETM-utilizing exercise programme to simulate a hypoxic environment, but future studies are needed to investigate whether repeated exposure to this condition provides similar benefits as altitude training in healthy adults.

Practical applications

The elevation training mask has been used in the health and athletic communities to improve performance. Although the company claims the beneficial effect of ETM on aerobic performance, the evidence is still debatable. Based on our results, wearing an ETM during high-intensity exercise (≥ 70% VO_{2max}) simulates modest hypoxaemia, but future studies are needed to determine whether this modest hypoxic condition can provide performance improvement. Additionally, professionals should consider the psychological discomfort (i.e., perceived breath effort) and delayed cardiac-autonomic recovery when designing an ETM-utilizing exercise programme for healthy adults.

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Disclosure statement

No potential conflict of interest was reported by the authors.

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Exhibit #23

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SHORT COMMUNICATION

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Effects of wearing N95 and surgical facemasks on heart rate, thermal stress and subjective sensations

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Abstract ***Aim***: The study was aimed at investigating the effects of wearing N95 and surgical facemasks with and without nano-functional treatments on thermophysiological responses and the subjective perception of discomfort. ***Method***: Five healthy male and five healthy female participants performed intermittent exercise on a treadmill while wearing the protective facemasks in a climate chamber controlled at an air temperature of 25°C and a relative humidity of 70%. Four types of facemasks, including N95 (3M 8210) and surgical facemasks, which were treated with nano-functional materials, were used in the study. ***Results***: (1) The subjects had significantly lower average heart rates when wearing nano-treated and untreated surgical facemasks than when wearing nano-treated and untreated N95 facemasks. (2) The outer surface temperature of both surgical facemasks was significantly higher than that of both N95 facemasks. On the other hand, the microclimate and skin temperatures inside the facemask were significantly lower than those in both N95 facemasks. (3) Both surgical facemasks had significantly higher absolute humidity outside the surface than both N95 facemasks. The absolute humidity inside the surgical facemask was significantly lower than that inside both N95 facemasks. (4) Both surgical facemasks were rated significantly lower for perception of humidity, heat, breath resistance and overall discomfort than both N95 facemasks. The ratings for other sensations, including feeling unfit, tight, itchy, fatigued, odorous and salty, that were obtained while the subjects were wearing the surgical facemasks were significantly lower than when the subjects were wearing the N95 facemasks. (5) Subjective preference for the nano-treated surgical facemasks was the highest. There was significant differences in preference between the nano-treated and untreated surgical facemasks and between the surgical and N95 facemasks. ***Discussion***: We discuss how N95 and surgical facemasks induce significantly different temperature and humidity in the microclimates of the facemasks, which have profound influences on heart rate and thermal stress and subjective perception of discomfort.

Keywords Facemasks · Nano-functional materials · Microclimate inside the facemasks · Subjective perception

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Introduction

Facemasks are critical components of personal protective equipment (PPE) for healthcare workers, particularly when those workers are dealing with transmitted diseases, such as the severe acute respiratory syndrome (SARS) outbreak that occurred in March 2003. Seto et al. (2003) performed a case study in five Hong Kong hospitals, involving 241 non-infected staff and 13 infected staff who were exposed to 11 patients with SARS, and they concluded that SARS was contagious by droplets. They suggested that the wearing of facemasks was of significance in reducing the risk of contagion after exposure to patients with SARS. Wong et al. (2004) reported a study on effective personal protective clothing (PPC) for healthcare workers attending patients with SARS. In the World Health Organization (WHO) (2003) and the US Centers for Disease Control (CDC) (2004) guidelines for PPE, facemasks with 95% filtration efficiency or above are required for healthcare workers exposed to SARS patients.

Hayashi and Tokura (2004) found that it was important to prevent an excessive increase of microclimate temperature and humidity inside the facemask in order to reduce heat stress on the body when farmers were spraying pesticides in a warm environment. Farquharson and Baguley (2003) reported that Emergency Department (ED) staff taking care of SARS patients at a hospital in Toronto wore double isolation gowns, a hair cap, an N95 facemask, a face shield and two pairs of gloves. ED staff had 12-h shift work while wearing N95 facemasks. Only one individual could take off his or her facemask at one time in an enclosed room. As soon as the staff had finished meals and drinks they had to wear the facemask again. Such situations made ED staff extremely stressed. Nielsen et al. (1987) found that the facemask air temperature significantly influenced thermal sensations of the whole body. Meyer et al. (1997) reported that the acceptable duration of wearing respiratory protective devices was about 1 h in a work environment with an air temperature of 18°C on average, and that the comfort sensation was reduced with increase of the air temperature. Similarly, White et al. (1991) found that the wearing of chemical protective clothing significantly reduced acceptable working time due to increased heat stress. These findings show clearly that serious heat stress occurs within the body when protective clothing is worn, which could cause workers to tire more easily and reduce their working time.

In a previous paper we reported that the N95 facemask had a filtration efficiency greater than 96% during wear, comparing surgical facemasks of 95% filtration efficiency (Li et al. 2004). Both N95 and surgical facemasks treated with nano-functional materials had significantly higher repellence to water, which can prevent droplets contaminated with viruses and bacteria from penetrating the facemasks by capillary actions during breathing cycles. Further, it has been shown that surgical facemasks treated with nano-functional materials have a significant ability to inactivate bacteria (Yao et al. 2004). It is important for one to know what impact the wearing of different types of facemasks has on heat stress and discomfort, as the filtration efficiency is similar between surgical and N95 facemasks, and whether the nano-functional treatment has an influence on heat stress and discomfort. In this paper, we report an experimental study on the effects of wearing different kinds of facemasks with and without nano-functional treatments on thermophysiological response and subjective perception of discomfort.

Methods

Subject

Ten healthy subjects, five men and five women, participated in the study, and their physical characteristics are summarized in Table 1. None was a smoker. Female subjects participated in the experiment only when they were during follicular phases.

Every participant was tested four times at the same time of day on four different days, wearing one of four types of facemasks. Before the first experiment the subjects were required to read an information sheet, on which the nature, purpose, method, and risks of the study were described, and then sign a consent form. They had the right to question any part of the procedure and to withdraw themselves from the experiment at any time without penalty. The human subjects ethics and sub-committee of The Hong Kong Polytechnic University approved the experimental protocol.

Facemasks

In the experiments we used four types of facemasks, including N95 (3M 8210) and surgical facemasks, which were treated with nano-functional materials to stop virus penetration by capillary action and to inactivate bacteria (Yao et al. 2004). Both facemasks are commercially available to hospitals and clinics in Hong Kong. The physical characteristics of the four types of mask are described in Table 2.

Physiological measurements

Skin and clothing microclimate (temperature, humidity) inside and outside the facemasks and inside shirts were continuously recorded by a logger (SCXI-1161, National

Table 1 Physical characteristic of human subjects

Characteristic	Male			Female		
	Average	SD	Range	Average	SD	Range
Age (years)	28.0	5.4	22–37	29.4	8.4	21–41
Weight (kg)	68.8	7.8	56–74	55.5	8.9	41–62
Height (cm)	172.5	6.8	164–180	168.2	7.4	151–170

Table 2 Physical characteristics of the masks

Mask type	Treatment	Size (cm)	Materials	Weight (g)	Thickness (mm)
N95	Untreated[a]	φ 12.5×13.2	Coverings: polypropylene	8.99	3.87
N95	Nano-treated[b]		and polyester	9.64	5.17
			Filter media: polypropylene		
Surgical	Untreated[a]	17.3×15.8	Outer and inner layers:	3.26	0.80
Surgical	Nano-treated[b]		polypropylene	3.39	0.85
			Middle layer: melt-blown		

[a]Normal facemasks
[b]Facemasks treated with nano-functional materials

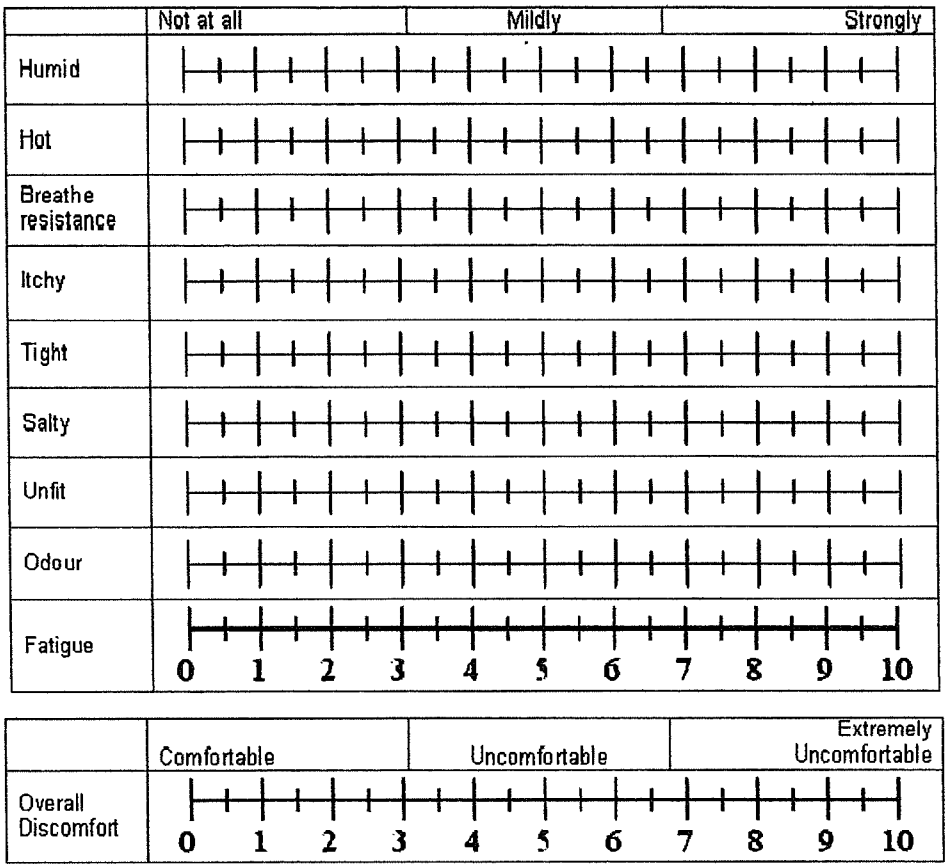
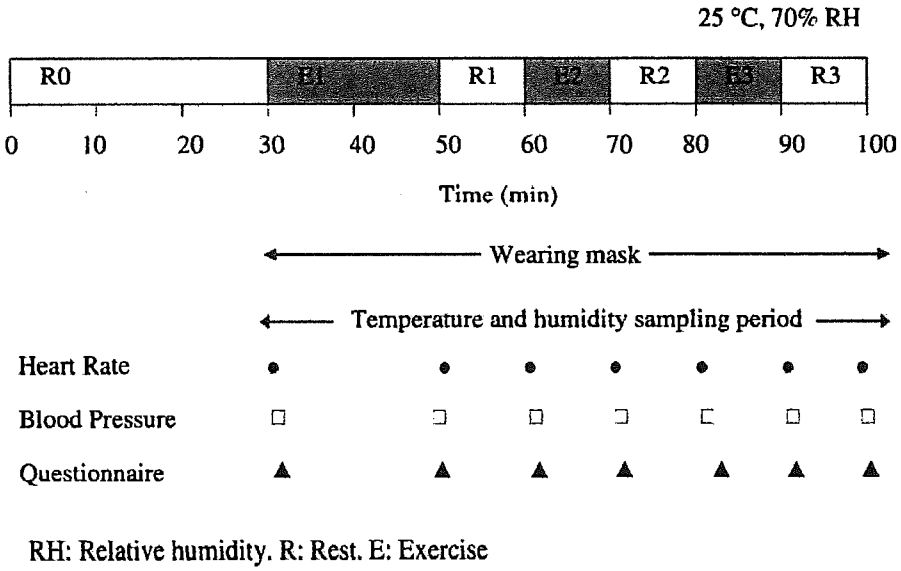


Table 3 Scale of measuring subjective perceptions

Instruments, USA) every 30 s. Sensors for the measurements of temperature and humidity inside shirts were fixed on the left and right chest regions. One uncovered sensor was attached directly to the skin. Facemask microclimate (temperature, humidity) and cheek skin temperature inside the facemasks were measured at the right cheek. Facemask microclimate (temperature, humidity) outside the facemasks was also measured at the right cheek. At the end of each exercise and rest period, heart rate and blood pressure were



RH: Relative humidity. R: Rest. E: Exercise

Table 4 The experiment schedule

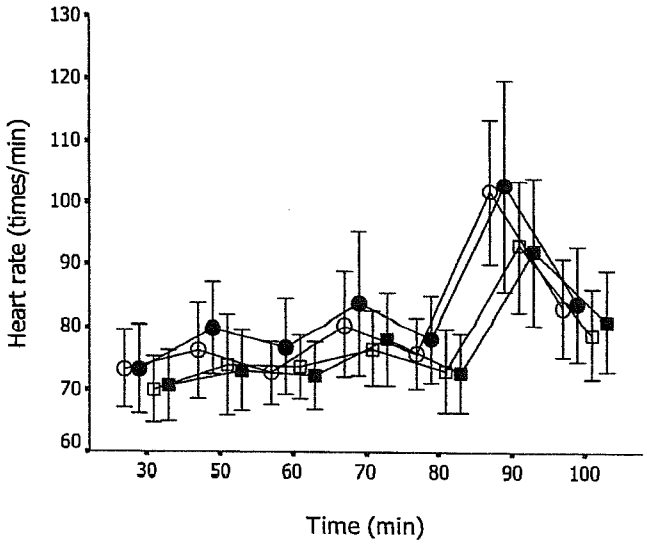


Fig. 1 Temporal changes in mean heart rate under the influence of the four kinds of facemasks. *Open circles* N95 facemask; *closed circles* nano-treated N95 facemask; *open squares* surgical facemask; *closed squares* nano-treated surgical facemask

measured with an upper-arm blood pressure meter (EW 3100, BMEW Ltd., Beijing).

Perception of discomfort

Subjects were required to rate their perceptions of ten sensations of discomfort: humidity, heat, breathing resistance, itchiness, tightness, saltiness, feeling unfit, odor, fatigue, and overall discomfort, at 30, 50, 60, 70, 80, 90 and 100 min. Table 3 shows the rating scales used by the subjects. In addition, at 100 min, the subjects were asked to reply to the question "How do you like the facemask?" by rating on a scale ranging from 0 to 10, with 0 representing "not at all", 5 representing "acceptable" and 10 representing "very fond of". This rating was used to obtain the preference of subjects for the four kinds of facemasks.

Experimental protocol

The experiments were carried out for 3 months from May to July. They were performed twice a day, one from 0900 h to 1100 h and another from 1500 h to 1700 h. The experimental protocol was randomized for men and women, and for the four types of facemasks.

A subject entered the climate chamber controlled at an air temperature of 25°C and a relative humidity of 70%, which is similar to the conditions in the hospitals. After body mass had been measured, the subject wore a 100% cotton T-shirt, short pants and sports sandals. Sensors were attached to different areas with surgical tape. Following a rest for 30 min on a chair (R0), during which time the subject was required to drink 500 ml water, the subject voided the bladder completely and put

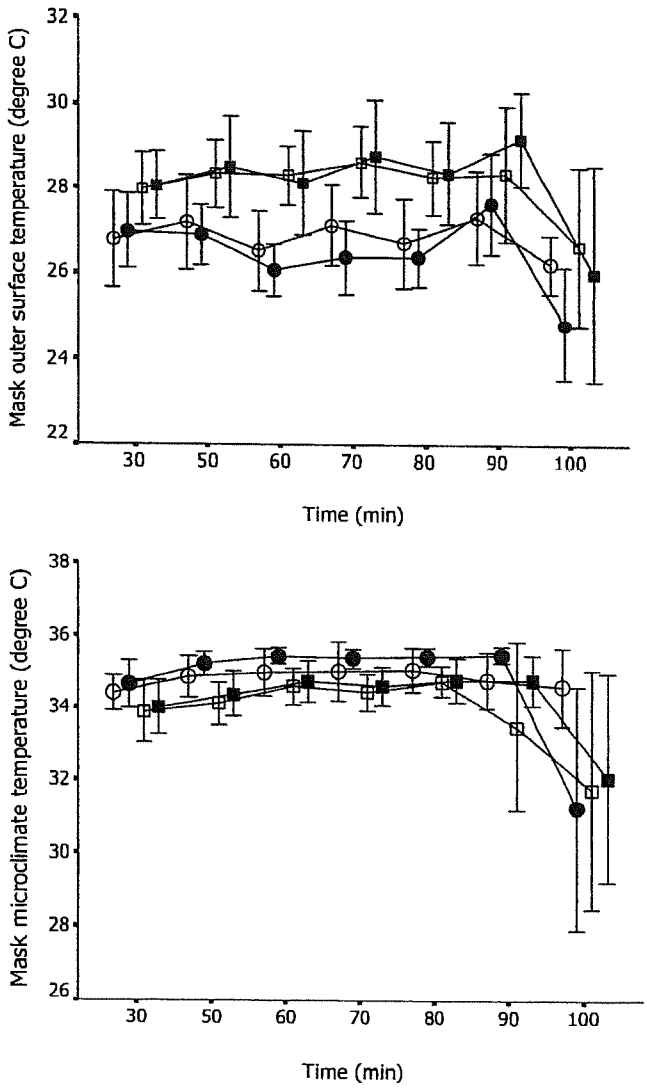


Fig. 2 Temporal change in mean temperature on the outer surface of the facemasks (*top*) and in the microclimate of the facemasks (*bottom*) under the influence of the four kinds of facemasks. *Open circles* N95 facemask; *closed circles* nano-treated N95 facemask; *open squares* surgical facemask; *closed squares* nano-treated surgical facemask

on a facemask, randomly selected. Then, the subject walked for 20 min at 3.2 km/h (E1) and took a rest for 10 min (R1); walked for 10 min at 4.8 km/h (E2) and took a rest for 10 min again (R2); and finally, the subject walked for 10 min at 6.4 km/h (E3) and took a rest for 10 min (R3). These workloads resembled approximately those performed by healthcare workers in a hospital ward. The schedule of the experiment is shown in Table 4. The participant took off the mask at 100 min, completing the whole experiment.

Statistical analysis

As mask microclimate temperature is a key parameter indicating thermal stress, we used this parameter to estimate the sample size. According to previous reports,

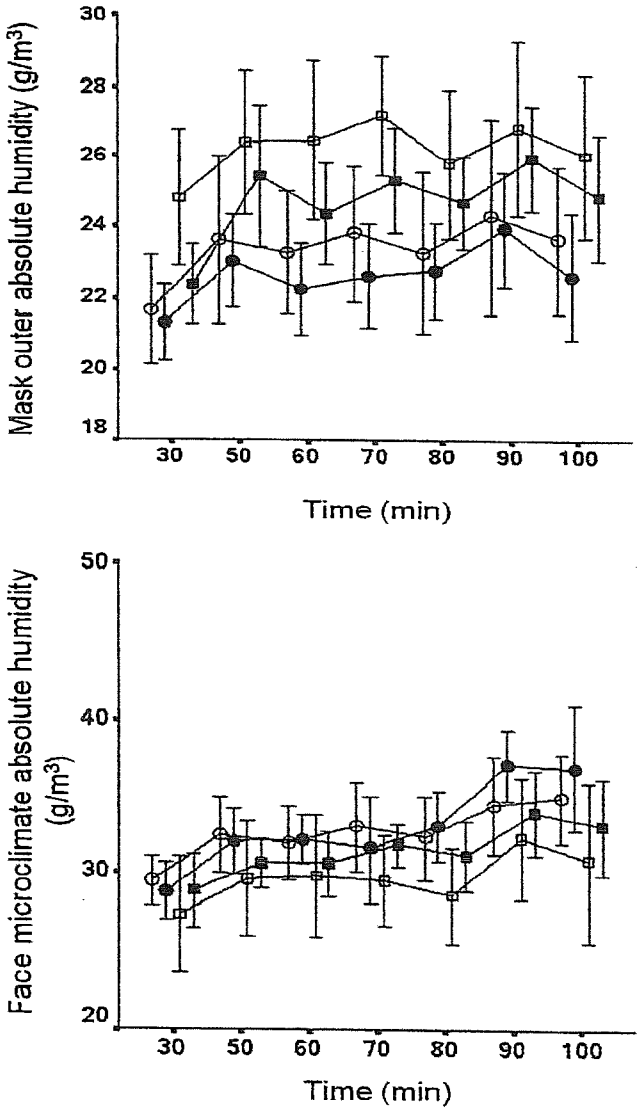


Fig. 3 Temporal changes in mean absolute humidity outside (*top*) and inside (*bottom*) the four kinds of facemasks. *Open circles* N95 facemask; *closed circles* nano-treated N95 facemask; *open squares* surgical facemask; *closed squares* nano-treated surgical facemask

the difference in microclimate temperature between masks is approximately 0.9°C and standard deviation is around 0.5°C (Hayashi and Tokura 2004). From this assumption, a sample size calculation reveals that ten participants are enough to reach an error of probability of $<5\%$ and a power of 90%.

Physiological parameters (including heart rate, temperature and humidity) and psychological responses (including perception of humidity, heat and breath resistance) were analyzed statistically. The influence of time, facemask type, nano-treatment, and their interactions on these human physiological and psychological responses were investigated by analysis of variance (ANOVA) and *t*-tests to determine whether the above factors had significant effect on the measured parameters.

Results

Physiological parameters

Heart rate

Figure 1 compares temporal changes of mean heart rates when the subjects were wearing the four kinds of facemasks. The pattern of changes in mean heart rate amongst these facemasks is similar, reaching peaks at the end of the third exercise session. The subjects had lower mean heart rates when wearing nano-treated and untreated surgical masks than when wearing nano-treated and untreated N95 facemasks. Significant differences were found among the four kinds of facemasks at the level of $P<0.01$ ($F=10.76$).

Temperature and humidity

Mask microclimate and face skin temperatures

Figure 2 shows temporal changes in temperatures on the facemasks' outer surfaces and in the facemasks' microclimates. The outer surface temperatures of both surgical facemasks were significantly higher than those of both N95 facemasks ($F=94.4$, $P<0.01$) (top of Fig. 3). On the other hand, microclimate temperatures inside the mask were significantly lower in both surgical masks than those in both N95 facemasks ($F=25.7$, $P<0.01$) (bottom of Fig. 3). The skin temperatures inside both surgical facemasks were significantly lower than those in both N95 facemasks ($F=40.7$, $P<0.01$).

Humidity outside and inside the facemask

Figure 3 (top) shows that both surgical facemasks had significantly higher absolute humidity on the outside surface than both N95 facemasks ($F=6.9$, $P<0.01$). The overall mean absolute humidity ± SD in nano-treated and untreated surgical facemasks was 24.7 ± 2.76 g/m^3 and 26.2 ± 2.74 g/m^3, respectively. The overall mean absolute humidity ± SD in nano-treated and untreated N95 facemasks was 22.7 ± 1.83 g/m^3 and 23.4 ± 2.74 g/m^3, respectively. Figure 3 (bottom) shows that the absolute microclimate humidity inside the surgical mask was significantly lower than inside both N95 facemasks. The overall mean absolute humidity ± SD in nano-treated and untreated surgical facemasks was 30.2 ± 4.32 g/m^3 and 28.64 ± 5.37 g/m^3, respectively. The overall mean absolute humidity ± SD in nano-treated and untreated N95 facemasks was 31.2 ± 5.47 g/m^3 and 31.8 ± 4.17 g/m^3, respectively.

Table 5 summarizes the influences of time, facemask, nano-treatment, and their interactions on physiological parameters (heart rate, blood pressure) and microclimate (temperature, absolute humidity) by ANOVA. For each parameter a multi-way analysis of variances was

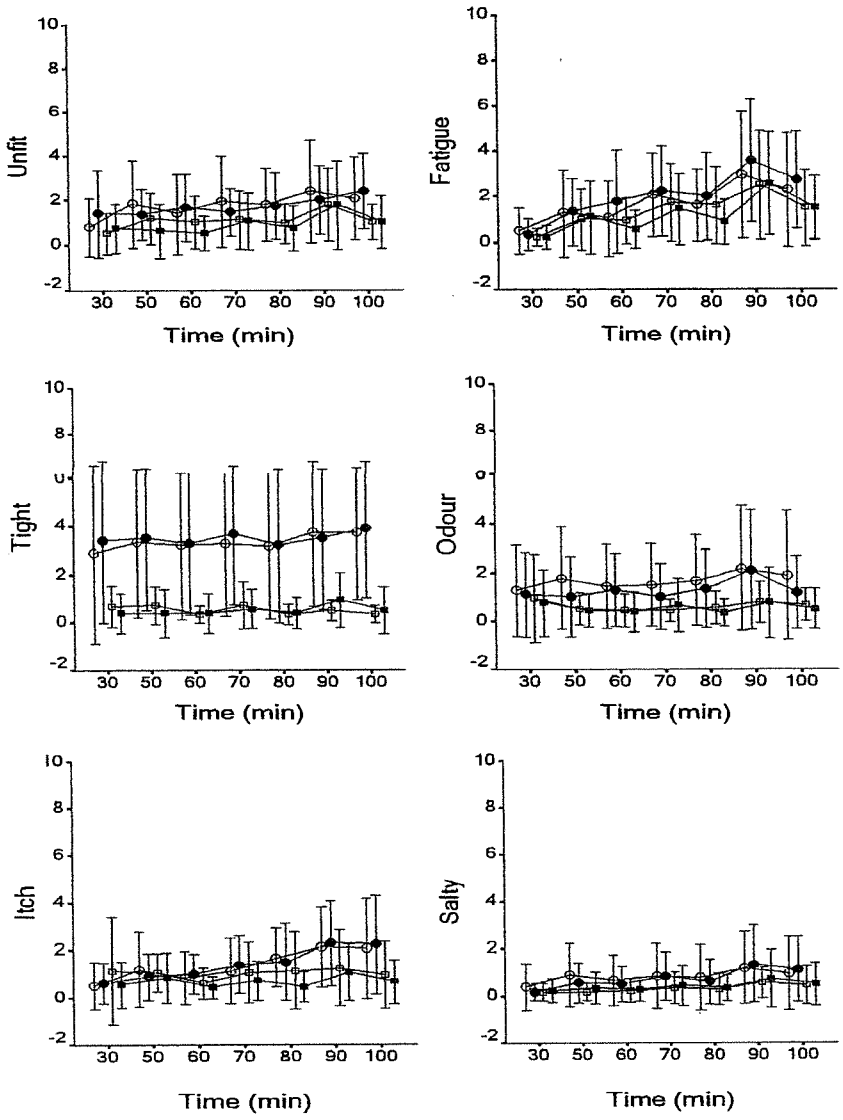


Fig. 5 Others sensations under the influence of the four kinds of facemasks: feeling unfit, tight, itchy, fatigued, odorous and salty. *Open circles* N95 facemask; *closed circles* nano-treated N95 facemask; *open squares* surgical facemask; *closed squares* nano-treated surgical facemask

resistance and overall discomfort increased gradually with time and increase of workload. Facemask type had great influence on the perception of humidity ($F=6.9$, $P<0.01$), heat ($F=15.4$, $P<0.01$), breath resistance ($F=15.0$, $P<0.01$) and overall discomfort ($F=23.1$, $P<0.01$). Both surgical facemasks had significantly lower ratings than the two N95 facemasks, which suggested that when wearing either of the surgical

Table 6 Influences of time, facemask, nano-treatment, and their interactions on various subjective sensations. $P>0.05$ is considered as being not significant and is shown as a dash. *Mask* type of facemask, *Treat* nano-treatment

Subjective sensations	*P* values						
	Time	Mask	Treat	Time × Mask	Time × Treat	Mask × Treat	Time × Mask × Treat
Humidity	0.000	0.000	–	–	–	–	–
Heat	0.000	0.000	–	–	–	–	–
Breath resistance	0.000	0.000	–	–	–	–	–
Itchy	0.017	0.002	–	–	–	–	–
Tight	–	0.000	–	–	–	–	–
Salty	–	0.001	–	–	–	–	–
Feeling unfit	0.047	0.000	–	–	–	–	–
Odorous	–	0.000	–	–	–	–	–
Fatiguing	0.000	0.011	–	–	–	–	–
Overall discomfort	0.000	0.000	–	–	–	–	–

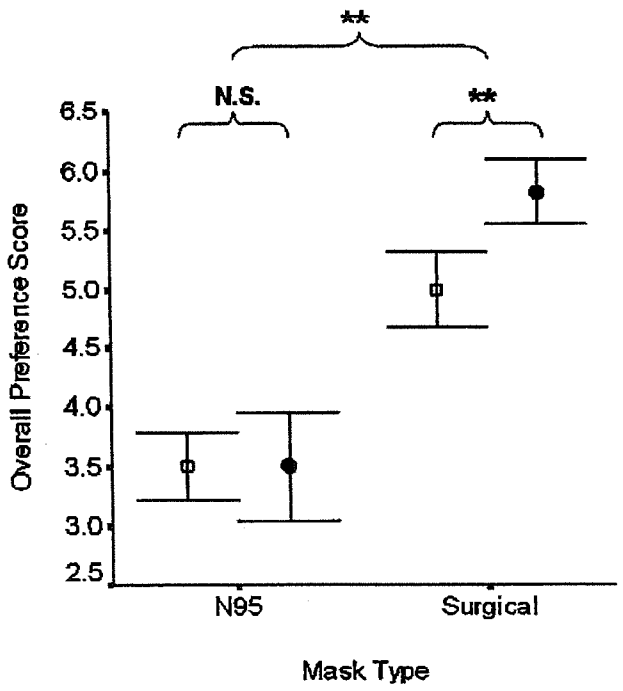


Fig. 6 Subjective preferences for the four kinds of facemasks

facemasks the subject felt drier, cooler, more able to breathe easily and less uncomfortable than when wearing either of the N95 facemasks. The ratings for humidity, heat, breathing resistance and discomfort of facemasks treated with nano-functional materials appear lower than those for untreated facemasks but are not statistically significant.

Figure 5 shows the subjective ratings for other sensations obtained while the subjects were wearing the facemasks. There are significant differences in the subjective perceptions feeling unfit ($F=5.3$, $P<0.01$), tight ($F=34.6$, $P<0.01$), itchy ($F=4.7$, $P<0.01$), fatigued ($F=2.7$, $P<0.05$), odorous ($F=7.9$, $P<0.01$) and salty ($F=3.9$, $P<0.01$). The ratings for those sensations were significantly lower when the subjects were wearing the surgical facemasks than when they were wearing either of the N95 facemasks, showing that the subjects felt less unfit, less tight, less itchy, less fatigued, less odorous and less salty with the surgical facemasks than with the N95 masks.

Table 6 summarizes the result of ANOVA, which show the influences of time, facemask, nano-treatment, and their interactions on subjective ratings for individual sensations and overall discomfort. Again, for each sensation, we carried out a multi-way analysis of variances to identify the statistical significance of the influences of the three variables: time, type of facemasks and nano-treatment, as well as their interactions. To save space, only the P values are used to show the statistical significance. A $P>0.05$ is considered as being not significant and is shown as a dash, and a $P<0.0005$ is considered as being significant and is marked as "0.000". As shown in Table 6, facemask type influences subjects' perception of all the nine individual sensations and overall discomfort significantly ($P<0.05$). On the other hand, all sensations were not significantly influenced by time and nano-treatment. There were no significant differences between ratings for tight, salty and odorous at different time periods.

Figure 6 shows the preferences of subjects for the four kinds of facemasks. Subjective preference for the nano-treated surgical facemasks is the highest, followed by the untreated surgical masks, the nano-treated N95 and then the untreated N95 facemask. There is a significant difference in preference between the nano-treated and untreated surgical facemasks and between the surgical and N95 facemasks. There is no significant difference in subjective preference between nano-treated and untreated N95 facemasks.

Discussion and conclusion

The results from the experiment demonstrate that heart rate, microclimate (temperature, humidity) and subjective ratings were significantly influenced by the wearing of different kinds of facemasks. Nielsen et al. (1987) observed that delivery of air with different temperatures into a facemask corresponded to the application of a local thermal stimulus to the skin surface around the mouth, nose and cheek. This local thermal stimulus also affected the heat exchange from the respiratory tract. In our investigation, microclimate temperature, humidity and skin temperature inside the facemask increased with the start of step exercise, which led to the different perceptions of humidity, heat and high breathing resistance among the subjects wearing the facemasks. High breathing resistance made it difficult for the subject to breathe and take in sufficient oxygen. Shortage of oxygen stimulates the sympathetic nervous system and increases heart rate (Ganong 1997). It was probable that the subjects felt unfit, fatigued and overall discomfort due to this reason. White et al. (1991) found that the increases in heart rate, skin temperature and subjective ratings may pose substantial additional stress to the wearer and might reduce work tolerance. This could be the reason why Farquharson reported that working 12-h shifts while wearing an N95 mask had indeed been a challenge to their ED staff (Farquharson and Baguley 2003).

Significant differences were observed between N95 and surgical masks. Mean heart rate, microclimate temperature, humidity and skin temperature inside the facemask, together with perceived humidity, heat, breathing resistance in the facemask, and itchiness, fatigue and overall discomfort, were significantly ($P<0.01$) higher for N95 masks than for surgical masks. In other words, the subjective perception of breathing difficulty and discomfort increased significantly with increasing thermal stress. This finding agrees with the observations reported by White et al. (1991). The surface

temperature outside the facemask was lower, and the temperature in the facemask microclimate was significantly higher, for the N95 masks than for the surgical masks (Fig. 3), indicating that the heat loss from the respiratory tract is more difficult to endure in N95 masks, inducing higher heat stress and perception of discomfort. This agrees well with the observations reported by Hayashi and Tokura (2004).

As the purpose of wearing the facemasks is to protect the wearers by filtering out viruses and bacteria, it is obviously questionable whether the surgical masks, which induce less heat stress and discomfort, can provide enough protection for healthcare workers. As reported previously, the in vivo filtration efficiency and physical properties of the masks were investigated at the same time (Li et al., unpublished data). During the simulation wear trials, in vivo filtration efficiency of N95 facemasks was 96%, in comparison with 95% for surgical facemasks. Furthermore, the surgical facemasks with significantly higher moisture permeability and air-permeability were thinner than the N95 facemasks, indicating that surgical facemasks should be more breathable and less humid and hot, which agrees with the in vivo measurements of temperature and humidity inside and outside the masks and the subjects' perception of breathing resistance and discomfort.

It is interesting to note that no significant difference was found between nano-treated and untreated facemasks for physiological measurements and subjective perceptions, even though nano-treated surgical and N95 facemasks were perceived to be slightly less uncomfortable. On the other hand, subjective preferences for the nano-treated surgical masks were significantly higher than those for the untreated surgical facemasks. This indicates that the nano-functional treatment of surgical and N95 facemasks does not have significant negative effects on the thermophysiological responses and subjective perceptions of discomfort.

Therefore, it can be concluded that N95 and surgical facemasks can induce significantly different temperatures and humidity in the microclimates of facemasks, which have profound influences on heart rate and thermal stress and subjective perception of discomfort.

Acknowledgments We would like to express our thanks to the Hong Kong Polytechnic University for supporting this research through projects A188, YD56 and G-YD80.

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Exhibit #24

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The Effect on Heart Rate and Facial Skin Temperature of Wearing Respiratory Protection at Work

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Twelve New Zealand workers from a range of occupations were studied to investigate the effect of wearing air-filtering respiratory protection on heart rate (HR) and facial skin temperature (T_{lip} and T_{cheek}) whilst working. All variables were measured continuously during simulated and actual work. The former allowed physiological measurements to be undertaken during the physical activities carried out during the work task without respirators and without exposure to hazardous airborne substances. Mean heart rates in subjects moving without respirators ranged from 75 to 94 beats/min and from 77 to 98 beats/min during respirator use at work. Mean skin temperature under the mask (T_{lip}) increased in 11 of the 12 subjects while using respirators (range 1.2–4.8°C) but T_{cheek} only increased in four (range 0.6–1.5°C). The use of simulated work tasks in the experiment was a compromise. The heart rate data from the real and simulated work indicated that effort and workload, though not identical, were similar. The increase in skin temperature under the mask may account for the reluctance of individuals to wear respiratory protection at work. This region of the face is very thermosensitive.

Keywords: heart rate; skin temperature; respiratory protection; respirators; respiratory protective devices; workplace; industry

INTRODUCTION

The response of individuals in the workplace to the use of respiratory protection is complex and not fully understood. Thermal discomfort has been suggested as a common reason for not wearing air-purifying respirators (Martin and Goldman, 1972; Houdous *et al.*, 1989; Laird *et al.*, 1993). In a New Zealand survey nearly one-third of those studied cited thermal discomfort and feelings of claustrophobia, possibly occasioned by increased temperature, as critical reasons for their reluctance to wear protective equipment (Laird *et al.*, 1993).

Previous laboratory studies (Nielsen *et al.*, 1987; Gwosdow *et al.*, 1989; White *et al.*, 1989; DuBois *et al.*, 1990) have indicated that a skin temperature around the mouth and nares of <34°C is acceptable to most individuals. However, once the skin temperature of this area exceeds 34.5°C, the sensation of thermal discomfort becomes unacceptable to many people (Gwosdow *et al.*, 1989; DuBois *et al.*, 1990). Emerson *et al.* (Emerson *et al.*, 1967) demonstrated that certain surgical masks caused as much as a 5°C increase in facial temperature and a later study found an increase of 7.5°C in lip temperature in subjects wearing disposable respirators (Jones, 1991). Whether such large increases in facial or lip temperature occur in the normal industrial setting as a result of respirator use or whether any such changes in skin temperature may be enough to influence user acceptability are unknown.

Our study looked at the effect of wearing a respirator on heart rate and facial skin temperature in individuals doing light work in workplaces in New Zealand. These individuals were considered to be typical of the majority of those wearing respirators in this country. The study consisted of a laboratory

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Table 1. The activities of the subjects studied and their respirator use

Group	Activity	Perceived exertion	Task duration (min)	No. of tasks/shift	Total daily respirator use (min)
1	Agricultural chemical spraying	L	20–30	4	80–120
2	Paint spraying	L	12–21	6	72–126
3	Sanding wood	M	5–7	10	50–70
4	Chemical mixing and preparation	M	12–13	5	60–65
5	Sanding precast fibreglass mouldings	H	10–11	8	80–88
6	Automotive paint spraying (panel beaters)	H	24–27	4	96–108

The subjects duration of respirator use and perceived exertion (L = light, M = moderate, H = heavy) was obtained from a previous questionnaire survey (Laird *et al.*, 1993).

investigation of the effect of wearing a respirator on facial skin temperature, followed by a workplace investigation of the effect of wearing a respirator on skin temperature and heart rate.

MATERIALS AND METHODS

All subjects taking part in both studies were fully informed about the experiments and the information that was sought before taking part, and all signed a consent form. The experiments had the approval of the Massey University Human Ethics Committee.

Laboratory study

A laboratory project was undertaken to investigate the effects of wearing a respirator on facial skin temperature during light sustained work in New Zealand climatic conditions before the field work was started. This was carried out on five Massey University staff members (two female, three male; age range, 31–47 yr; height, 1.78 ± 0.06 m; mass, 75 ± 8.8 kg). They had all previously experienced using respirators. They were reasonably fit but not undergoing athletic training. On two occasions, separated by at least 24 h, the subjects worked on a friction-braked cycle ergometer (Monark, Ergomedic 818E) at 50 W for 30 min. Wet and dry bulb ambient air temperatures were recorded using a standard whirling hygrometer (T8716, Casella, London, UK).

In the first experiment the subjects wore a standard filter type respirator for the first 15 min. In the second, the respirator was worn for the second half of the exercise period only. The respirator covered the mouth and nose, but not the eyes or cheeks. Facial skin temperature was recorded at 1 min intervals throughout using bead thermistors bonded to 15 mm alloy plates. One thermistor was positioned on the cheek, 20 mm anterior to the external auditory meatus, and a second was placed on the upper lip directly below the left nare. Mean heart rate was also recorded using a body-borne heart rate monitor (Sports Tester: PE 3000, Polar Electro, Finland). The data obtained during the last 5 min of each 15 min experimental situation, when the subjects were approaching a steady state, were compared using a variance ratio test and paired Student's *t*-test.

The heart rate monitor was calibrated against a standard isolated ECG amplifier (NT 117, Neomedix Systems, Sydney, Australia) and cardiac rate meter (Jrak BioSignals Ltd, Windsor, Victoria, Australia). It was accurate to within ±1.0%. The thermistors were calibrated against a mercury-in-glass thermometer between 20 and 40°C.

Workplace study

There were 12 male subjects divided into six groups of two on the basis of their occupation. All had been doing the tasks that were evaluated for at least 3 months before the study began. The subjects were selected from the questionnaire investigation (Laird *et al.*, 1993) on the basis of their perceived workload: four judged that their work was hard, four moderate and four light. Physical details of the subjects are shown in Table 1.

Each subject wore a four-channel cassette tape recorder (Oxford Instruments Medilog Series 4.24, Cambridge, UK) to record the facial skin temperatures that were measured in the laboratory study. A fourth channel was for timing. Mean heart rate was recorded using a heart rate monitor, as before.

Environmental variables. The thermal environment at the workplace was measured before and after each experiment. Ambient air temperature and relative humidity were measured using a standard whirling hygrometer (T8716, Casella). Radiant energy was measured with a globe thermometer (T6480, Casella) and air velocity using a hot wire anemometer (TA 3000; Air Flow Instruments, High Wycombe, UK).

Protocol. The experiments were carried out in six workplaces during part of a normal working shift. The duration of the work task for which a respirator was required was variable (Table 1). However, most subjects were required to wear a respirator for between 1 and 2 h in a normal working day. Following instrumentation and a time delay to allow the subjects' heart rates to return to a resting level (5–15 min), the

Table 2. Subject-by-subject analysis of the effect of the respirator on lip temperature (°C)

	Experiment 1			Experiment 2		
Subject	Resp.	No resp.	*P*	No resp.	Resp.	*P*
A (f)	33.8 ± 0.5	34.3 ± 0.2	(**)	30.8 ± 0.3	32.8 ± 0.4	***
B (f)	31.6 ± 0.4	29.0 ± 0.3	***	28.8 ± 0.5	32.2 ± 0.2	***
C (m)	34.5 ± 0.4	32.3 ± 0.2	***	30.8 ± 0.8	32.7 ± 0.4	***
D (m)	36.8 ± 0.1	36.4 ± 0.1	***	35.0 ± 0.4	35.5 ± 0.2	***
E (m)	35.0 ± 0.4	34.7 ± 0.1	***	33.2 ± 0.3	34.8 ± 0.3	***

Values are the mean ± SD of 15 readings taken at 1 min intervals.
**$P < 0.01$; ***$P < 0.001$; f = female, m = male; () = increase in temperature on removing the respirator; resp., respirator.

subjects were asked to simulate the work task without wearing a respirator and then to carry out the task whilst wearing their respirator. Throughout the experiment the subjects were continuously observed by one of the authors (I.S.L.) to ensure that the type of movement undertaken, postures adopted and duration of each section of the task were similar in the two situations.

Analysis of data. Skin temperature was obtained by replaying the tapes using a tape data analyser (Medilog, Cambridge, UK) and passing the data into a Maclab A/D converter (Chart version 3.0 software; ADI Instruments, Sydney, Australia). The time pulses on the tape were also digitized to enable temporal coordination between the heart rate and temperature data.

Statistical analysis was carried out in two ways: (i) data from each subject during simulated (without respirator) and actual (with respirator) work were compared; and (ii) the population statistics of the 12 subjects were examined. The variance ratio test and Student's *t*-test were used for both analyses. Within-subject variance was not included in the population analysis.

Heart rate (HR) was analysed both as work/resting heart rate ratio and as the percentage of 'heart rate reserve' (% HRR) to allow comparison with previous investigations. The latter was calculated from the formula given by Louhevaara *et al.* (Louhevaara *et al.*, 1985):

$$\% \text{ HRR} = (\text{HR}_{\text{work}} - \text{HR}_{\text{rest}})/(\text{HR}_{\text{max}} - \text{HR}_{\text{rest}})$$

HR_{max} was estimated from the formula given by Jones (Jones, 1991) as 210 − 0.66 × age. All results are expressed as the mean ± 1 SD.

RESULTS

Laboratory study

In the first experiment the mean temperature of the lip dropped from 34.3 ± 1.9 to 33.3 ± 2.8°C when the respirator was removed midway through the exercise period (n.s.). In the second experiment it increased from 31.7 ± 2.4 to 33.6 ± 1.5°C on putting the respirator on ($P < 0.01$). The mean working heart was significantly higher during the first experiment (115.8 ± 12.6 versus 106 ± 11.6; paired *t*-test, $P = 0.024$). Wearing the respirator had no significant effect on heart rate or on the temperature of the cheek in either experiment. The dry air temperature in the laboratory ranged between 18.5 and 21.5°C, and relative humidity between 48 and 67% during the experiments. There were no significant changes in the environment between the two sets of experiments.

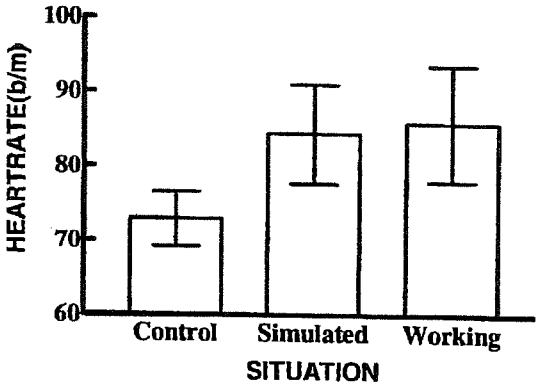

Fig. 1. The effect the of simulated and actual work with and without a respirator on the pooled heart rate data (error bars are ±1 SD).

Analysis of data on a subject-by-subject basis revealed that the lip temperature was significantly decreased following the removal of the respirator in four of the five subjects in experiment 1 and increased by donning it in all five subjects in the second experiment (Table 2).

Workplace study

The experiments were performed in spring/early summer. The dry air temperatures during the experiments ranged from 17 to 24°C. There were no significant differences between the airflows or relative humidity measured at the different work sites. Air velocity was low, ranging from 0.01 to 0.1 m/s; relative humidity was high, at 60–80%. The subjects wore the clothes that they used habitually. Half wore

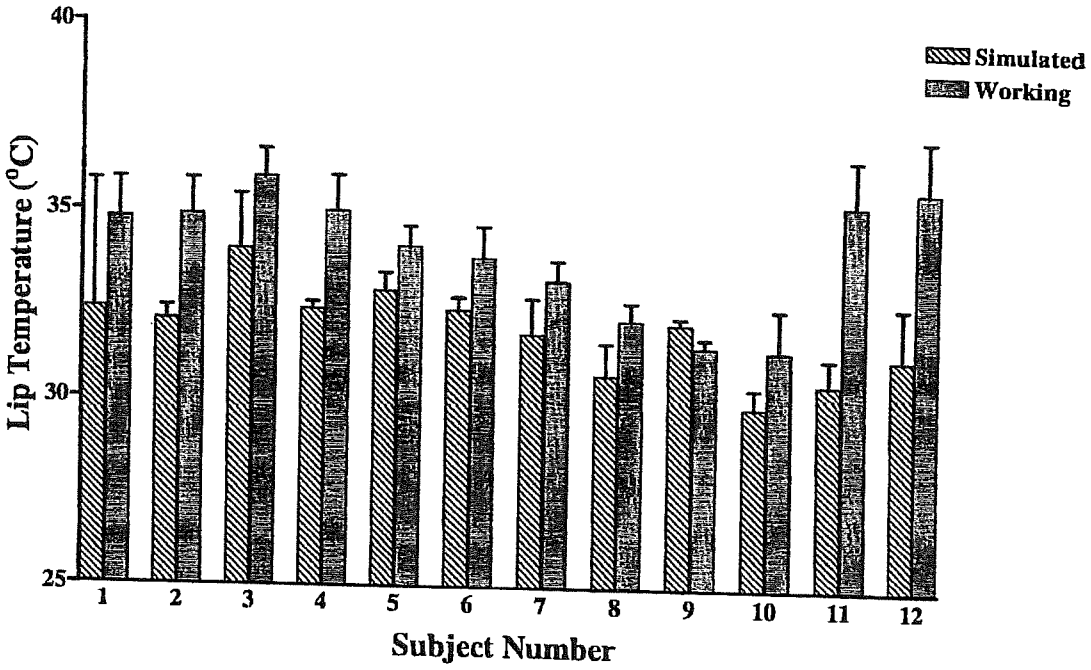

Fig. 2. The effect of the simulated and actual task on the skin temperature of the upper lip (error bars are ±1 SD).

overalls over normal clothing; the remainder wore just their ordinary clothes, with or without dust coats over them.

Heart rate changes. The subjects had resting heart rates of 73 ± 3.7 beats/min. On simulating the work, the subjects' heart rates increased to 84 ± 6.6 beats/min (range = 75–94; equivalent to 5–20% HRR). Subsequent performance of the task whilst wearing the respirator resulted in a heart rate of 88 ± 7.7 beats/min (range = 77–98; equivalent to 6–22% HRR). The paired Student's *t*-test indicated that the population heart rate was significantly increased above resting rate for both simulated (without respirator) and real (with respirator) tasks ($P < 0.001$), but the difference between simulated and real was of marginal significance ($P = 0.04$). Subject-by-subject analysis showed that the heart rate increased more in the real task than in the simulated task in five of the 12 subjects. These increases were small (range = 2.1–4.5 beats/min) when compared with the overall effects of activity (mean = 12 beats/min).

Examination of the heart rate data expressed as a percentage of heart rate reserve (Fig. 1) showed that the subjects were working at 10.1 ± 4.8% HRR during the simulated task and 11.4 ± 5.7% HRR during the actual task. With the exception of the two automotive panel beaters, who worked at 21.8 and 23.7% HRR (work/resting heart rate ratio = 1.34 and 1.4), the work level of the subjects in the study could be classified as light (% HRR = 9.8 ± 2.2; range = 6.3–14.9; work/resting heart rate ratio = 1.15 ± 0.03, range = 1.08–1.18).

Facial skin temperature. The population mean cheek temperature during real work wearing the respirator was not significantly different from the simulated work (32.2 ± 1.38 versus 31.9 ± 1.23°C). Cheek temperature was unrelated to environmental temperature ($r^2 \approx 0.02$). The population mean lip temperature during real work was significantly higher than during simulated work (33.8 ± 1.56 versus 31.87 ± 1.12°C; two-tailed Student's *t*-test, $P < 0.001$). Subject-by-subject analysis indicated this lip temperature increase was significant ($P < 0.05$ in 11/12 subjects; $P < 0.001$ in 7/12). The lip temperature rose above 34.5°C in six individuals (Fig. 2).

DISCUSSION

Laboratory study

The results of the laboratory study showed that fitting a respirator during a period of continuous work led to an increase in facial skin temperature under the mask, while removing the mask tended to decrease it. With the caveat that work in industry is usually intermittent, this suggests that removal of a respirator whilst continuing to work may create a sense of thermal relief.

Workplace study

To the authors' knowledge, this study is the first to examine the effect of filter-type respirators on heart rate and facial skin temperature in the workplace setting in New Zealand. Three aspects of the investigation merit discussion: (i) the use of simulated work; (ii) the heart rate responses and work level of the subjects; and (iii) the skin temperature changes induced by wearing a respirator mask.

The use of simulated work. The use of data from a simulated work task was a scientific compromise since there were two variables (no respirator versus respirator; simulated task versus actual task) and only two series of measurements. A more critical experiment would have been to have the subjects perform the real work task without a respirator or have them perform the simulated task twice—with and without the respirator.

Though individuals frequently do work that requires respirator use without wearing such protection (Harris, 1974; Aucoin, 1975; National Coal Board, 1977; Corn, 1980; Laird *et al.*, 1993), it was considered to be unethical to ask workers to do this as part of a scientific investigation. Repetition of the simulated work would have caused even more disturbance and loss of output; this too was considered to be unacceptable for the sake of better data. Since all the subjects had been engaged in the tasks for which the respirators were required for at least 3 months, it was considered likely that the work levels could be accurately simulated. Statistical analysis of the data suggested that this was not the case. The subjects worked a little harder when they performed their real work. This once again underlines the difficulty of extrapolating results from simulated to real situations.

Heart rate responses and work level. The workloads of the individuals investigated were relatively low when compared with previous studies of the workplace. In only two subjects was the workload in the order of 20% HRR. The rest of the subject heart rates fell within the range of 6.3–14.9% HRR, which were markedly lower than those studied by Louhevaara *et al.* (1985), who found that heart rates of respirator users in industry varied from 15 to 57% HRR. With the exception of the panel beaters, the ratio of working to resting heart rates ranged between 1.08 and 1.18. This is lower than those frequently reported in studies of other industries, including open hearth workers (ratio 1.64; Minard *et al.*, 1971), nurses (1.45; Fordham *et al.*, 1978), car assembly workers (1.45; Goldsmith *et al.*, 1978), cane cutters (1.38; Vitalis, 1981) and steel workers (1.37; Vitalis *et al.*, 1994). However, we selected the subjects for the study to span the range of perceived exertion scored in a questionnaire survey (Laird *et al.*, 1993) and these work rates are probably typical for respiratory users in light industry in New Zealand. This raises the question of the relevance to the general workplace of laboratory studies of respirators where high fixed heart rates or even $\dot{V}O_{2max}$ (Johnson *et al.*, 1995) were used.

Skin temperature changes induced by the wearing of a respirator mask. This study consistently demonstrated a significant increase in the skin temperature of the upper lip when subjects fitted a respirator and carried out a task in the workplace. A face mask prevents normal transpiration and cooling of the skin, and is filled with warm, moist expired air throughout most of the breathing cycle. This may increase skin temperature irrespective of workload. The increases we observed under the respirator were between 1.2 and 4.8°C in 11 of the 12 subjects. These were lower than reported in earlier studies (Emerson *et al.*, 1967; Jones, 1991), perhaps because of the relatively low work rates of the subjects. However, the effect was sufficient in six individuals to increase skin temperature to >34.5°C (Fig. 2)—a level which may induce unacceptable sensations of thermal discomfort (Gwosdow *et al.*, 1989; DuBois *et al.*, 1990). This group included all the subjects engaged in spraying, who were working harder as judged by heart rate (four of these had working heart rates of >95 beats/min). On this basis, the larger rise in lip temperature seen in these subjects could possibly be a result of increased ventilation.

Many workers occasionally remove respirators when their use is required or are reluctant to wear them at all (Laird *et al.*, 1993). From our study, thermal discomfort may contribute to this. Possible solutions are use of silicone materials (DuBois *et al.*, 1990), or perhaps cooling and draining the respiratory device. Whether, for short periods of respirator wear, the simple expedient of putting the respirator in the refrigerator before use might help is a matter of conjecture.

CONCLUSIONS

Two principal conclusions emerge from the study. First, wearing a respirator whilst working, whether continuously in the laboratory or in industry, produced a significant increase in skin temperature under the mask. For some subjects in the workplace this was sufficient to be likely to cause thermal discomfort. The large changes in skin temperature caused by respirators may provide one explanation for the reluctance to use them. Secondly, the work undertaken by the subjects that were studied in the workplace was light, despite some having classified it as moderate or hard in a questionnaire survey.

Saudi women covers the whole face except the eyes and is thus maybe capable of causing facial mask like short-term physiological responses. In fact, increased breathing discomfort during summer is a common complaint among our *niqab* wearing subjects corroborating previous studies.[19,22] No data is available on the air and moisture permeability of the layers of fabric used in making the *niqab*. It has been reported that use of two different kinds of facemasks with 95% and 96% filtration efficiency, can result in different mean heart rate, microclimate temperature, humidity and skin temperature under facemask, together with perceived discomfort, fatigue and breathing resistance.[7] In light of these previous findings, it is reasonable to speculate that the present result of lower VF values in veil group than non-veil group, is not only due to direct airway resistance caused by *niqab*, but increase in microclimate temperature, humidity and skin temperature inside the *niqab* can be contributing factors. In addition, it is a possibility that part of the exhaled carbon dioxide may also be trapped inside the *niqab*, leading to some shortage of oxygen causing an increase in heart rate via sympathetic nervous system.[24]

Furthermore, the use of *niqab* in presence of known sedentary life style of Saudi females probably does not require extra respiratory effort to overcome physiological responses to the use of *niqab*, as these ladies may adapt to shallow breathing patterns with higher heart rate. Prolonged reduction of pulmonary ventilation during the use of *niqab* for several hours may result in lowering the tidal volume, which may induce insufficient oxygenation and inadequate carbon dioxide elimination. This affects gas exchange[15] and thus can cause some degree of hypoxia, which may lead to different musculoskeletal pain disorders and reduction in endurance levels. We can also speculate that the regular use of *niqab* by Saudi women can probably be one of the reasons of higher prevalence of fibromyalgia and cervicobrachialgia among Saudi females.[25]The present results of lower VF values in veil group than non-veil group, merit further investigations where different physiological responses, blood oxygen saturation levels and subjective perception of discomfort should be investigated during different levels of physical activity with *niqab* made of different air and moisture permeability.

In conclusion, our data show that there are differences in VF tests among *niqab* and non-*niqab* wearing Saudi adult females, where values for *niqab* users are lower than the values for those who do not use *niqab*. Further studies are required to investigate the effect of different fabric materials with different air and moisture permeability that can safely be used for *niqab* with minimal effect on ventilatory function.

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Exhibit #25

Original Article

Effect of face veil on ventilatory function among Saudi adult females

Ahmad Alghadir[1], Farag Aly[2], Hamayun Zafar[3]

Abstract

Objective: The use of face veil called "*niqab*" by women to cover their faces at public places is a common practice in some Muslim communities. The long-term effect of *niqab* use on ventilatory function (VF) has not previously been reported. The aim of this cross-sectional study was to compare VF between *niqab* wearing and non-*niqab* wearing healthy Saudi females.

Methodology: Thirty eight healthy adult Saudi females participated in this study. Nineteen subjects were regular *niqab* users and the other nineteen were either not using *niqab* at all or used it for less than one hour per day. Forced vital capacity (FVC), forced expiratory volume in one second (FEV1), FEV1/FVC (%), and maximal voluntary ventilation (MVV) were recorded using a digital spirometer.

Results: Mean values of FVC, FEV1, FEV1/FVC (%) and MVV for *niqab* wearers were significantly lower than the corresponding values for non-*niqab* wearers. Significant negative correlation was found between the FVC and FEV1 values and the number of hours of the use of face veil per day.

Conclusions: Long-term use of traditional *niqab* use can affect VF.

KEY WORDS: Face veil, Ventilatory function test, Saudi, Healthy, Adult, Females.

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INTRODUCTION

Free and unobstructed airflow in the upper and lower respiratory tract during inspiration and expiration is a prerequisite for normal respiratory function. Any pathological or non-pathological condition that can compromise free airflow during respiratory cycle can result in hypoventilation with increased respiratory effort that can lead to physiological burden involving cardiovascular[1-3] and temperature regulatory system,[1] and can also cause psychological stresses.[4]

A large body of knowledge exists about possible mechanisms and short- and long-term physiological responses for different pathological airflow limiting conditions, involving the respiratory system endogenously, such as obstructive sleep apnea,[5] chronic obstructive pulmonary disease and asthma.[6] However, studies on physiological responses to external airflow limiting factors such as surgical and protective masks, are relatively few. Use of facemasks of different air permeability can cause changes in temperature and humidity in the microclimates of the facemasks, causing different effects on heart rate, thermal stress and perception of discomfort.[7] It is also shown that 1-4 hours use of surgical masks during surgeries can result in decreased arterial oxygen saturation levels and increased pulse rate in surgeons.[8]

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In some Muslim communities, women use face veil called "*niqab*" to cover their faces at public places. The use of *niqab* is more common in Arab gulf countries, and in Saudi Arabia it is a cultural norm and a social obligation for Saudi women to wear *niqab* at public places. Due to the similarity in which the use of facial mask and *niqab* can interfere with the normal airflow during respiration, it can be reasonable to draw an analogy between the use of facial masks and *niqab* with regard to the physiological responses. However, to the best of our knowledge, no previous data on physiological impact for short- or long-term use of *niqab* on the VF is available.

The spirometry data can help to study respiratory function and dysfunction in different conditions and diseases affecting the airflow in lungs during respiration,[9] and can also provide information about breathing reserve and exercise tolerance to determine fitness levels of healthy subjects.[10] For spirometry, the most commonly used parameters are vital capacity (VC), forced vital capacity (FVC), forced expiratory volume in one second (FEV1), and maximal voluntary ventilation (MVV). The VC is the maximum volume of air that can be expelled from the lungs after a maximum inspiration, FVC is the volume of air that can forcibly be blown out after full inspiration, FEV1 is the maximum volume of air that can be forcibly blown out in the first second during the FVC manoeuvre, and MVV is the maximum volume of air that can be inhaled and exhaled in one minute.[11] These VF values are gender dependent with lower values in females.[12]

We have previously shown that the parameters of VF tests in Saudi subjects are lower than the Caucasian reference values, and these gender related differences for Saudi adults is larger than corresponding differences in Caucasian population.[13] Based on the analogy between the use of facial masks and *niqab* with regard to the physiological responses, it can be assumed that the long-term use of *niqab* can have an impact on the VF of its user. It is hypothesized that the VF values would be lower for face veil users than non-face veil users.

The aim of this study was to compare VF values off face veil users and non-face veil users among healthy Saudi adult females.

METHODOLOGY

Subjects: Thirty eight healthy Saudi females (aged 18-31 years; mean age 24) participated in this study. Nineteen subjects were regular *niqab* users (minimum of 3 years for 4 hours per day) (veil group), and nineteen subjects were either not using *niqab* at all or for less than one hour per day (non-veil group). Users of any tobacco products and obese subjects with body mass index (BMI) >25kg/m^2 were excluded. General characteristics of subjects are shown in Table-I.

Measurements and Procedures: This study was performed at the Cardiopulmonary Laboratory, CAMS, King Saud University. The standing height without shoes (cm), and weight (kg) for calculation of BMI, and age and number of hours of *niqab* use per day was noted for each subject. The investigation was approved by the Ethics committee of Rehabilitation Research Chair, King Saud University. All subjects gave their informed consent to be part of the study. The VF tests were conducted in accordance with 'Guidelines for Standardization of Spirometry'[14] using a portable spirometer Pony Fx (COSMED, Rome, Italy). Subjects were given detailed information about all test procedures and were asked to practice the test manoeuvre before the actual test. The spirometer was calibrated daily and tests were conducted between 9 am to 12 noon to minimize diurnal variation,[15] at room temperature between 20-25°C. The FVC, FEV1, and MVV were recorded while subjects were seated comfortably in a chair. The FEV1/FVC% was later calculated. Each manoeuvre was performed for three to five times by every subject, and the largest value for each parameter was selected.[14]

Statistical Analysis: Mean and SD were used for descriptive statistics. The FVC, FEV1, FEV1/FVC (%) and MVV mean values for the face veil group and non-face veil group were compared by one-tail unpaired t-test with a significance level of

Table-I: Mean, standard deviation (SD) and range of age, weight, height and BMI for healthy face veil and non-face veil using Saudi women (n = 19, each group).

Subjects	*Age range (years)*	*Age (mean± SD)*	*Weight Range(kg)*	*Weight(kg) (mean± SD)*	*Height range (cm)*	*Height(cm) (mean± SD)*	*BMI range (kg/m2)*	*BMI (mean± SD)*
Non-face veil group (n= 19)	19-31	24.4 ± 2.9	51-74	58.5 ± 6.7	152-168	158.3 ± 4.8	19.4-28.5	23.3 ± 1.9
Face veil group (n=19)	18-31	23.7 ± 3.2	50-79	59.8 ± 7.0	149- 180	159.1 ± 6.9	19.3-27.4	24.0 ± 2.4
p -value		0.74		0.26		0.94		0.93

Table-II: Mean, SD and statistical comparison between mean values of different VF parameters for healthy face veil and non-face veil using Saudi women (n = 19, each group).

Parameters	*Non-face veil group (mean± SD)*	*Face veil group (mean± SD)*	*Mean difference*	*% of difference*	*p-value*
FVC (litres)	3.4 ± 0.3	2.6 ± 0.4	0.8	30 %	<0.001
FEV1 (litters/sec)	2.6 ± 0.5	1.9 ± 0.3	0.7	28%	<0.001
FEV1/FVC (%)	80.6 ± 3.6	72.6 ± 3.1	8.0	9%	<0.001
MVV (litres/min)	62.9 ± 9.0	45.6 ± 7.6	17.3	28%	<0.001

FVC= Forced vital capacity, FEV1= forced expiratory volume in one second, MVV= maximal voluntary ventilation.

<0.05. The Pearson product moment correlation coefficient test was used to test the presence of any linear relationship between the number of hours of veil use per day and the values of VF parameters. The software SPSS version 10, was used for all statistical analyses.

RESULTS

Table-II shows the mean and SD values of FVC, FEV1, FEV1/FVC (%) and MVV for face veil and non-face veil groups. The values for all parameters were significantly lower in veil group than the non-veil group.

Correlation statistics revealed significant negative relationship between number of hours of wearing face veil per day and FVC (r=0.9, p-value = 0.0001) and the FEV1(r=0.8, p-value = 0.0001), respectively. However, correlation between number of hours of wearing face veil per day and FEV1/FVC (%) (r=0.215, p-value = 0.19) and MVV (r=0.188, p-value =0.22) was not significant.

DISCUSSION

To the best of our knowledge, this is the first study on the effect of *niqab* use on the ventilatory function. The present results show that VF values (FVC, FEV1, FEV1/FVC (%) and MVV) for *niqab* wearing females were significantly lower than the corresponding values for non-*niqab* wearing females. In fact, the FVC, FEV1 and MVV values were approximately 30% lower, and the FEV1/FVC (%) was 9% lower for *niqab* wearing females. The data also show a significant negative correlation between the duration of *niqab* use and the FVC and FEV1 values.

It is reasonable to believe that any condition, pathological or otherwise, which can interfere with the free airflow in the respiratory system or adequate expansion of lungs and chest wall, can result in insufficient ventilation or excessive work of respiratory muscles to maintain required ventilation. Previous studies show that different conditions limiting chest expansion during respiration, such as obesity, scoliosis or use of bullet proof vests, body armour and heavy backpacks can reduce FVC and FEV1, without affecting the FVC/FEV1 ratio.[16-18] These results indicate a proportionate reduction in FEV1 and FVC values. However, our present results show that FEV1/FVC% value for *niqab* wearing females was significantly lower than the non-*niqab* wearing females. This indicates that with long-term use of *niqab*, the FEV1 was relatively reduced more than the FVC.

Although data on the changes in VF related to different pathological airflow limiting conditions such as obstructive sleep apnea,[5] chronic obstructive pulmonary disease and asthma[6] are available, but data on changes in VF related to non-pathological airflow limiting conditions with use of protective masks are not available. A few previous studies on the use of facial masks[7,8] only reported short-term physiological responses (heart rate, thermal stress and oxygen saturation). Thus, our present data add new knowledge on the effect of long-term use of *niqab* on VF.

It has been reported that with increased physical activity the temperature in the facemask microclimate increases,[7,19] causing increase in thermal sensations of the whole body[20], which decreases work endurance.[21] The temperature of air entering the facemask during inspiration corresponds to thermal stimulus to the skin under mask and affects heat exchange from the respiratory tract, reducing breathing comfort sensation.[22] Decrease in blood oxygenation level among surgeons has also been reported following the use of surgical masks during surgery lasting 1 to 4 hours,[8] and long duration use of facemasks by medical emergency staff has been related to extreme stress.[23]

Taken together, it is reasonable to believe that the short-term physiological responses to the use of *niqab* maybe similar to those previously described for different kinds of facial masks. It can be argued that unlike the facial masks, the *niqab* is usually not very tightly applied to the face, and thus the thermal and circulatory changes that occur when wearing a surgical mask may not be applicable. However, in comparison to the facial masks that cover mainly the nose and mouth, the *niqab* used by

Saudi women covers the whole face except the eyes and is thus maybe capable of causing facial mask like short-term physiological responses. In fact, increased breathing discomfort during summer is a common complaint among our *niqab* wearing subjects corroborating previous studies.[19,22] No data is available on the air and moisture permeability of the layers of fabric used in making the *niqab*. It has been reported that use of two different kinds of facemasks with 95% and 96% filtration efficiency, can result in different mean heart rate, microclimate temperature, humidity and skin temperature under facemask, together with perceived discomfort, fatigue and breathing resistance.[7] In light of these previous findings, it is reasonable to speculate that the present result of lower VF values in veil group than non-veil group, is not only due to direct airway resistance caused by *niqab*, but increase in microclimate temperature, humidity and skin temperature inside the *niqab* can be contributing factors. In addition, it is a possibility that part of the exhaled carbon dioxide may also be trapped inside the *niqab*, leading to some shortage of oxygen causing an increase in heart rate via sympathetic nervous system.[24]

Furthermore, the use of *niqab* in presence of known sedentary life style of Saudi females probably does not require extra respiratory effort to overcome physiological responses to the use of *niqab*, as these ladies may adapt to shallow breathing patterns with higher heart rate. Prolonged reduction of pulmonary ventilation during the use of *niqab* for several hours may result in lowering the tidal volume, which may induce insufficient oxygenation and inadequate carbon dioxide elimination. This affects gas exchange[15] and thus can cause some degree of hypoxia, which may lead to different musculoskeletal pain disorders and reduction in endurance levels. We can also speculate that the regular use of *niqab* by Saudi women can probably be one of the reasons of higher prevalence of fibromyalgia and cervicobrachialgia among Saudi females.[25]The present results of lower VF values in veil group than non-veil group, merit further investigations where different physiological responses, blood oxygen saturation levels and subjective perception of discomfort should be investigated during different levels of physical activity with *niqab* made of different air and moisture permeability.

In conclusion, our data show that there are differences in VF tests among *niqab* and non-*niqab* wearing Saudi adult females, where values for *niqab* users are lower than the values for those who do not use *niqab*. Further studies are required to investigate the effect of different fabric materials with different air and moisture permeability that can safely be used for *niqab* with minimal effect on ventilatory function.

ACKNOWLEDGEMENTS

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Exhibit #26

SEE IT: NYPD commissioner bashes city leaders as 'cowards' in police brass...

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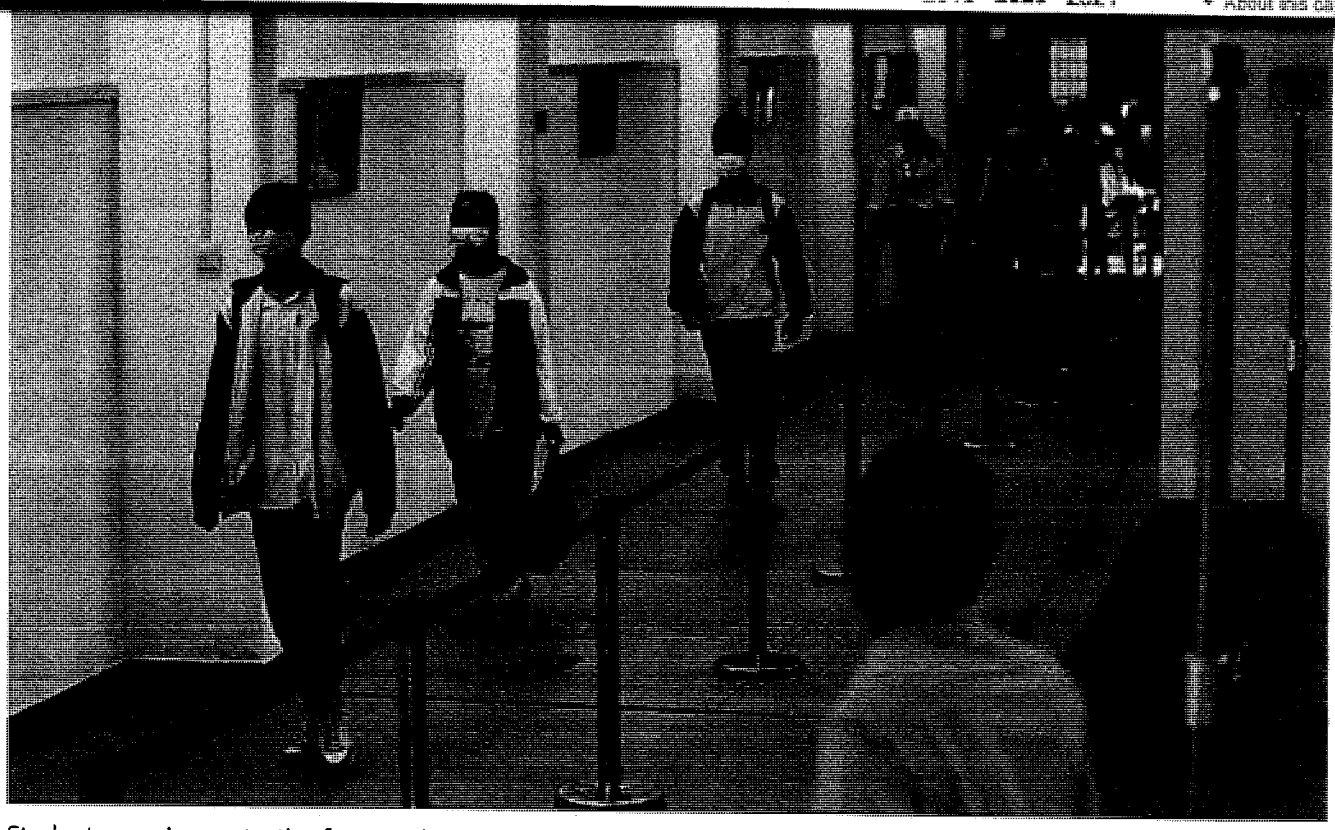
Alex Rodriguez. Ieni simply don't | buy and then

CORONAVIRUS

Two Chinese boys reportedly die within week of each other while wearing face masks in gym class

By JESSICA SCHLADEBECK
NEW YORK DAILY NEWS | MAY 07, 2020



Students wearing protective face masks to help curb the spread of the new coronavirus walk in social distancing as they arrive to a high school in Wuhan in central China's Hubei province, Wednesday, May 6, 2020. (AP)

Two schoolboys in China reportedly collapsed and suddenly died within a week of each other after they were forced to participate in gym class while sporting face masks.

The students, both 14 years old, were running laps as part of their schools' required physical examination tests when they both unexpectedly dropped dead, according to Australian outlet 7News.

The pair of incidents, which occurred just six days apart, have prompted calls to cancel the term's running exams amid coronavirus concerns and possible breathing difficulties brought on by the face masks — which are required to be worn by many governments worldwide in a bid to slow the illness' spread.

One of the teens had only just begun the physical exam when he collapsed on April 24 at Dancheng Caiyun Middle School, located in the Henan Province in central China, according to his stepfather, who was identified as Mr. Li.

"It happened within two to three minutes during his PE class. He was wearing a mask while lapping the running track, then he suddenly fell backwards and hit his head on the ground," Li told 7News.

His death certificate listed the cause as sudden cardiac arrest, but no autopsy was performed. Li believes the mask his son had been required to wear played a factor in his tragic passing.

"It was sunny and their PE class was in the afternoon when it was at least 20 degrees

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The student had only just returned to school four days earlier — the first time children have been allowed back in their classrooms since they were shuttered by the Chinese government in January.

His funeral was held on April 30, the same day a second boy died under similar circumstances at Xiangjun Future Experimental School in Changsha, the capital of central China's Hunan province. He was reportedly participating in a 1,000 meter running exam and wearing an N95 mask when he dropped dead on the track.

China's major cities, including Wuhan — the original epicenter for coronavirus — have been gradually returning to normal in recent days. However, most foreigners are still banned from entering the nation.

Ahead of their reopening, many schools in China have spaced out desks and organized smaller classroom sizes to protect against COVID-19. In addition to face masks, students are also required to have their temperatures checked and those with results that are too high are not allowed in the building.

With News Wire Services

Exhibit #27

Original Article

Is safeguard compromised? Surgical mouth mask harboring hazardous microorganisms in dental practice

Rohan Sachdev[1], Kriti Garg[2], Garima Singh[3], Vishal Mehrotra[2]

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Abstract

Context: Dental personals are more prone to acquire infections through saliva and aerosols. Surgical masks (SMs) are used by dental professionals to reduce microorganism shedding from the mouth, nose, and face of the patient. **Aims:** This aim of the study is to assess the bacterial and fungal presence and their prevalence over the contaminated surgical mask in dental practice. **Settings and Design:** This study was conducted with sample size 240 used surgical masks collected from 130 dental personnel. **Subjects and Methods:** A cross-sectional questionnaire survey was conducted with analysis involved inoculation of external and internal surfaces in an enrichment media for isolation of bacteria and fungi. Group of isolated bacteria and fungi were preliminarily identified by morphology and using Gram's stain and lacto-phenol cotton blue mediums. Data were analyzed using paired *t*-test; the significant level of $P < 0.050$. **Results:** Microbiological analysis of samples revealed bacteria *Staphylococci* 26.35% as a predominant species followed by *Pseudomonas* 17.82% and *Streptococci* 15.50%. *Aspergillus* fungal species was also present in 6.97%. Mean ± SD of bacterial and fungal contamination on inside/outside area of the used masks was 48 ± 26 and 180 ± 110 cfu/ml/piece and 14 ± 6 and 32 ± 13 cfu/ml/piece, respectively, $P < 0.001$. The used surgical masks from dental department personnel working outpatient dental department had relatively higher bacterial and fungal contamination than the other dental departments. **Conclusions:** To reduce a load of microorganism contamination in the clinical environment, more awareness campaigns should be implemented in daily routine and air quality of dental departments should be improved with necessary protective measures.

Keywords: Dental department, dental personal, microbial contamination, surgical mask

Introduction

In hospitals and dental clinics, the major risk of infection for healthcare workers and dental professionals is the transmission from patients, through contaminated instruments or pieces of equipment and the hospital surroundings.[1,2] In hospital-acquired infections, surgical site infections (SSIs) and dental clinics play a role in more than 20% of infections.[3,4] It is by the Centre for Disease Control and Prevention that 2.7% of surgical procedures are complicated by patient working areas because of the presence of various infections.[5] With over 6 billion microbes/ml of saliva colonizing in every individual's oral cavity, the dental clinic is an axis of microbial pursuit. To maintain international guidelines and precautions for infection control, various protective measures have been taken to control the contamination of the dental clinics and to protect the patient and the dental personal. The significant part of infection control is the clinician's mouth mask which acts as a strike to microorganisms from the touch of possibly contaminated hands to the contaminated aerosols due to routine ultrasonic scaling and high-speed handpieces.[6,7]

Spooner JL in 1967 in his review mentioned that Weaver and Capps were the first who described in 1915 that face masks are effective against contagious disease as well as cross infections.[8] In the dental clinics, the dentist mouth mask, major protective

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equipment comes in direct closeness to the patient and is an area of significant concentration of the aerosol but the literature available showed that the surgical mouth mask might not be sufficient to protect the person from air-borne pathogens and might also be the origin of various air-borne and droplet infection.[9,10] Hence, the present study was conducted to assess the bacterial and fungal presence and their prevalence over the contaminated surgical mask in dental practice.

Subjects and Methods

This study was conducted to assess the bacterial and fungal contamination and their prevalence on 240 used surgical face masks (face mask earloop triple-layered non-woven polypropylene) from 130 dental personnel during the 2 months period from September to November 2019. The participants of the study were of both genders aged 20 to 40 years, and have voluntarily participated and gave the signed consent form. The study was conducted with the ethical approval of the ethical committee. A cross-sectional survey was conducted using a self-administered questionnaire, consisting of seven questions used to assess the knowledge and practice of participants regarding the use of mouth mask.

The 130 dental clinic participants were working from different departments such as: Department of oral medicine and radiology, department of oral and maxillofacial surgery, department of pedodontics, department of endodontics, department of periodontics, and dental emergency room of the college. Their used surgical masks maximum of 30 min duration, which were 240 in total, were collected in sterile zip lock pouches to culture and analysis of the bacterial and fungal counts on the inside and outside surface of the mouth masks. Inside and outside surface of the mouth masks were separated by sterile technique and put in a sterile container consisting of trypticase soy broth for 25 min. A spread plate method was used for determining total bacterial and fungal counts. General bacteria of the specimen are cultivated in a plate count agar (PCA) and general fungi of the specimen are cultivated in a Sabouraud 4% dextrose agar (SDA). The plates were incubated at 37°C for 48 h to get the bacterial counts, and incubated at room temperature for 7 days for fungal counts. The observation was done daily for 10 days. With the method given by Larone 1995, preliminarily identification of microorganism's species present was done by Gram's stain and microscopic morphology (lactophenol cotton blue) of the isolated bacteria and fungi was performed.[11] After incubation, the bacterial and fungal colonies were counted and calculated to express as colony-forming unit/m3 (cfu/m3) by a formula as follows:

Total counts (colony-forming unit/m3 or cfu/m3) = [Total colonies × 1000]/250

Collected data of the study were analyzed using Statistical Package for Social Sciences (SPSS) software version 17 using descriptive frequency method. Results are represented as frequency and percentage to estimate the prevalence of antimicrobial agents present in the samples as well the responses of participants. Mean and standard deviation (SD) for describing bacterial and fungal counts were analyzed using the paired *t*-test and to compare between the mean of microbial contamination on the outside and inside areas of used masks.

Results

A total of 240 used surgical masks were collected in the present study from 130 dental professionals from various departments to assess the bacterial and fungal contamination. Out of 130 participants, 73 were males and 57 were females. Questionnaire variables analysis revealed that 66.9% of participants wear their mouth-masks while working at chair-side and about 33% wear them all the time. 67.6% of the study participants keep their mouth

Table 1: Participants response based on questionnaire

Variables		Results n (%)
Gender (*n*-130)	Male	73 (56.1)
	Female	57 (43.8)
Time period of wearing mouth mask	Only Chairside	87 (66.9)
	Whole working time in clinics	43 (33)
Frequency of changing mouth mask	For every patient	89 (68.4)
	Once daily	41 (31.5)
Practice of exchanging mouth mask with friends	Yes	35 (26.9)
	No	95 (73)
Storage of mouth mask	Working apron pockets	25 (19.2)
	Books	17 (13)
	Instrument tray	88 (67.6)
Working on the case without mouth mask	Yes	55 (42.3)
	No	75 (57.6)
Awareness regarding used mouth mask causing cross-contamination if touched once	Yes	111 (85.3)
	No	19 (14.6)
Disposal of mouth mask with household waste	Yes	21 (16.1)
	No	109 (83.8)

Exhibit #28

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ORIGINAL ARTICLE

Surgical masks as source of bacterial contamination during operative procedures

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KEYWORDS
Hospital-acquired infection;
Surgical mask;
Surgical site infection

Abstract *Background:* Surgical masks (SMs) are used to reduce bacterial shedding from the mouth, nose and face. This study aimed to investigate whether SMs may be a potential source of bacterial shedding leading to an increased risk of surgical site infection.
Methods: Bacterial contamination of the SMs was tested by making an impression of the external surface of the mask on sterile culture media immediately. We investigated the difference in bacterial counts between the SMs worn by surgeons and those placed unused in the operating room (OR), and the bacterial count variation with indicated wearing time. Moreover, the difference in bacterial counts on the external surface between the first and second layers of double-layered SMs was also assessed.
Results: The bacterial count on the surface of SMs increased with extended operating times; significant difference was found between the 4- to 6-hour and 0-hour groups ($p < 0.05$). When we analysed the bacterial counts from the same surgeon, a significant increase was noted in the 2-hours group. Moreover, the bacterial counts were significantly higher among the surgeons than the OR. Additionally, the bacterial count of the external surface of the second mask was significantly higher than that of the first one.
Conclusions: The source of bacterial contamination in SMs was the body surface of the surgeons rather than the OR environment. Moreover, we recommend that surgeons should change the mask after each operation, especially those beyond 2 hours. Double-layered SMs or those with excellent filtration function may also be a better alternative.

Abbreviations: CDC, Center for Disease Control; CFU, Colony-Forming Unit; HAI, Hospital-Acquired Infection; SM, surgical mask; SSI, surgical site infection; TJA, Total Joint Placement.

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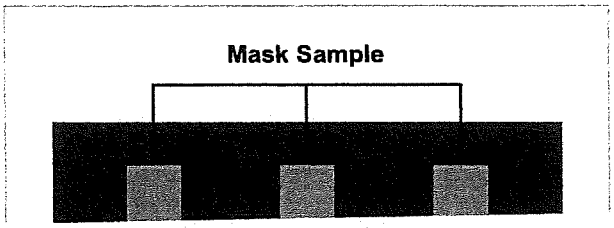
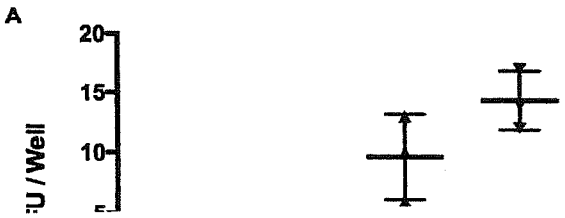




The translational potential of this article: This study provides strong evidence for the identification that SMs as source of bacterial contamination during operative procedures, which should be a cause for alarm and attention in the prevention of surgical site infection in clinical practice.

Introduction

Hospital-acquired infections rank among the top 10 leading causes of hospital deaths in the United States, and surgical site infections (SSIs) contribute to more than 20% of them [1]. It is estimated by the Center for Disease Control and Prevention that 2.7% of surgical procedures are complicated by SSI [2]. It is generally accepted that SSI is one of the most common and costly postoperative complications leading to increased morbidity, mortality, length of stay, hospital readmission and hospital costs [2–4]. Particularly in orthopaedics, SSI after total joint placement (TJA) can be devastating and a costly complication [5,6]. Moreover, an increasing number of TJAs are performed yearly [7], the rate of which has been estimated to range from 0.2% to 2% [8]. Given its heavy economic burden on the patient and health-care system [9], it is of utmost importance to find ways to reduce SSI.

Prevention of SSIs is a goal of surgeons in the operating room (OR); controlling airborne contamination and reducing microbial shed from personnel may help decrease the incidence of SSIs. Controlling airborne contamination is not difficult, especially if a laminar flow system of ventilation is present, which can significantly purify the air and reduce bacterial load [10,11]. In addition, a proper surgical attire, including the use of surgical gowns, sterile gloves, surgical hats and masks to the maximum extent, prevents microbial shed from the surgical personnel [12,13]. The surgical attire aims to provide a functional barrier between the surgical team and patient. However, the efficacy of the surgical attire, such as surgical masks (SMs), in preventing SSI is often unclear [12]. Given that the overall prevalence of SSIs is low, a large number of participants or procedures must be included for a study to prove the efficacy of a particular intervention; thus, many of the current practices have limited literature support [14].

The present study discusses the role of SMs as potential sources of bacterial load, contaminating the surgical work higher filtration reduce external surface contamination of masks?

Materials and methods

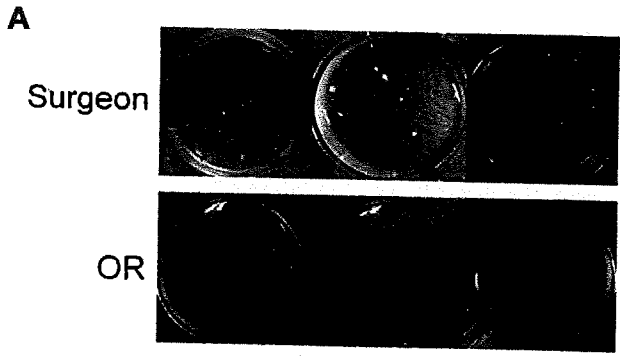
The study was performed in the OR. The study team consisted of four surgeons, a student and a microbiologist. The student cultivated the bacteria in the agar plate and counted the colony-forming units (CFUs). In this experiment, a single-blind was used, wherein the student did not know which group the SMs are from.

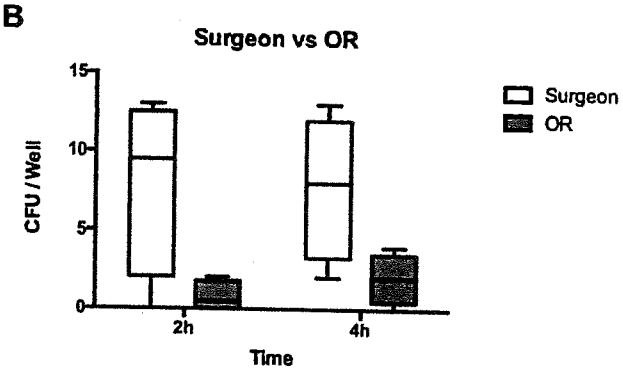
Forty cases of TJA were enrolled in this study. We divided the total surgical procedures into the following groups: 0- to 2-hours, 2- to 4-hours, 4- to 6-hours and no SM-used groups. After TJA, the SMs were put into sterile bags and submitted to the student. The surfaces of the SMs were cut, on an average, into three parts, and an impression was made on the sterile agar plate on a clean bench and incubated for 48 hours in an aerobic humid atmosphere at 37°C. The CFUs were then counted. We investigated the degree of contamination of SMs at different surgical stages, and the difference of bacterial counts between the SMs worn by surgeons and those unused in the OR. We also assessed the difference in the counts between the surfaces of single- and double-layered SMs.

Statistical analysis

The results are expressed as the mean ± standard deviation. Statistical differences were analysed using one-way analysis of variance followed with Dunnett *post hoc* test; "*" indicates a significant difference ($p < 0.05$), and "**" indicates a highly significant difference ($p < 0.01$).

Results





C

Unpaired t test	Significantly different?	P value summary	P value
Surgeon vs. OR (2h)	Yes	*	0.04639572
Surgeon vs. OR (4h)	No	ns	0.055666885

Figure 4 Mask contamination from the masks used by surgeon and unused masks in the OR. (A) Representative CFUs on the agar plate. (B) Analysis of the CFUs. (C) *p* values. CFUs = colony-forming units; OR = operating room.

Discussion

An increasing number of TJAs are performed yearly in orthopaedic departments. SSI is the most common complication associated with TJA, which results in a heavy economic burden on the patients and health-care system [16,17]. Therefore, finding measures to reduce SSI is of utmost importance. The laminar flow system of ventilation and surgical attire have been used during surgical procedures in the OR over the past several decades. Over the past 50 years, the surgical attire has remained relatively unchanged. This uniform has traditionally been thought to play two roles: to protect scrubbed personnel from exposure to body fluids and to maintain the sterility of the surgical field. However, whether the measures in the prevention of bacterial shed from the surgical personnel can become the source of bacterial contamination is worth being discussed. Here, we report that the SMs may be the potential sources of bacterial contamination with the progression of surgical procedure (Supplemental Figure 1). Generally, bacterial contamination has been used as an adjunct measure of SSI, commonly measured by airborne or settled CFU counts [12].

In this present study, we firstly examined the bacterial contamination of SMs with various wearing time in the OR. The SMs were collected from four surgeons, and the mean number of CFUs showed an increased trend with extended wearing time, yet without significance. However, when we analysed the data within the same surgeon, significance could be identified almost between any two groups. Thus, we concluded that the SMs were clean before wearing and get contaminated once they were used, and the contamination became more severe with extended wearing time in the OR. Meanwhile, high variation in this assay might be because of the different hygienic practices among the surgeons.

This identification raised another question on whether the bacteria of the SMs came from the surgeon shed or from air-borne contamination. To answer this question, surgeons who wore SMs were categorised in the surgeon-wearing group, while those SMs placed separately in the OR at the same time were classified as OR positioned groups (parallel control). The results showed that the masks from the surgeon groups had more CFUs than those in the OR groups. Interestingly, it is notable that a significance could be identified in the 2-hours group than in the 4-hours group. Thus, we concluded that the bacteria on SMs was more likely from the surgeon rather than from the OR air-borne contamination, especially in the early period.

Furthermore, now that SMs could bear more bacteria with extended wearing time and could become the source of shed-induced infection during operation, masks with higher filtration might be an effective tool to reduce bacterial contamination. To verify this hypothesis, surgeons were asked to wear two SMs simultaneously. Masks closed to the faces were named the first layer, and the outer layer masks were named as the second layer. The present results indicated that the CFUs significantly declined in the second masks, which means that the double-layered masks significantly reduced the contamination of the external surface of SMs. Thus, we concluded that wearing double-layered SMs might be an effective, low cost and easy measure in the prevention of bacterial shedding during operations.

In summary, the topic of SMs in the OR has been controversial. The scientific study to support the OR policies surrounding this topic is marginal. The purpose of this study was to investigate whether the SMs is a potential source of bacterial shedding, which may lead to the understanding of the causes of SSI. Based on our research, we mainly draw three conclusions: (1) SMs could be the source of bacterial shedding with extended wearing time; thus, we recommend that surgeons must change his/her mask in every operation interval; (2) bacteria on the external surface of the SMs are more likely from surgeons, which might be related to the surgeons' hygienic practices; thus, we recommend that surgeons must give more emphasis on face-mouth cleanliness and personal hygiene and (3) high-filtration masks, such as double-layered masks, could be an effective measure in reducing mask contamination.

Indeed, although a direct correlation between mask and SSIs has not been proven in the literature, the theory of aseptic technique is founded on the premise that a reduction in bacterial contamination will reduce the prevalence of SSI. Moreover, as the saying goes: "Do not think any virtue trivial, and so neglect it; do not think any vice trivial, and so practice it". Especially in TJA operations, taking

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Exhibit #29

People with lung conditions should NOT wear face masks if it makes it hard to breathe, Asthma UK cautions as hot air and tight fit can trigger symptoms

UK Government now recommends masks when in close proximity to others
Asthma UK tells asthmatics 'if you are finding it hard, then don't wear one'

By SAM BLANCHARD SENIOR HEALTH REPORTER FOR MAILONLINE
PUBLISHED: 14:39 EST, 18 May 2020 | **UPDATED:** 07:09 EST, 22 July 2020

People who have asthma or other lung conditions should not wear a face mask if it makes it difficult for them to breathe, Asthma UK has said.

The British Government is now advising people to wear face coverings if they are out in places where it is difficult to stay at least two metres (6'6") away from others.

This is because the coronavirus is a respiratory virus, meaning it infec it is breathed in and attaches to cells inside the airways and the lungs

But people who have asthma or illnesses such as chronic obstructive sease (COPD) or cystic fibrosis may find masks or face coverings m them to breathe.

Experts say people should wear a mask if they comfortably can, to pr themselves and others around them, but not risk their own health in t

Mask-wearing in certain situations in public is now mandatory in many countries in Europe, including France, Germany, Austria, Czech Republic and Slovakia (Pictured: Three staff members put on masks as they prepare to return to work at a bar in Berlin)

In its official guidance, Britain's Cabinet Office now says: 'If you can, wear a face covering in an enclosed space where social distancing isn't possible and where you will come into contact with people you do not normally meet. This is most relevant r short periods indoors in crowded areas, for example, on public transport or in some shops.'

But it adds: 'Face coverings should not be used by children under the age of 2 or those who may find it difficult to manage them correctly. For example, primary age children unassisted, or those with respiratory conditions.'

Respiratory conditions are illness that interfere with someone's breathing such as asthma, chronic obstructive pulmonary disorder (COPD), cystic fibrosis, chronic bronchitis, emphysema or lung cancer.

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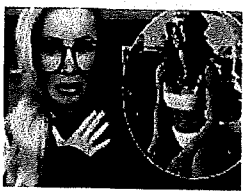
Wearing a mask, experts say, can make it harder to draw air into the lungs and make symptoms of those conditions worse.

Asthma UK says: 'For some people with asthma, wearing a face cover be easy. It could make it feel harder to breathe.

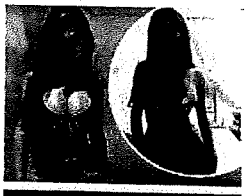
he government has advised that people with respiratory conditions wear face coverings, so if you are finding it hard, then don't wear one

DON'T MISS

'People are losing their families and you're on the beach telling us we don't know how hard it is': Olivia Attwood slams influencers for saying they're 'working' abroad



Demi Rose sends temperatures soaring as she dons a black swimsuit and gold bikini in sizzling Instagram posts
Wow



Jennifer Lopez, 51, showcases her breathtaking figure in a racy green halterneck swimsuit as she reminisces on her Turks and Caicos trip

Amir Khan's wife Faryal Makhdoom calls UK government a 'dictatorship' over new rules for those travelling in Dubai... after going with COVID symptoms!

Little Mix cut former member Jesy Nelson OUT of their behind-the-scenes music video for Sweet Melody after her shock exit
Bye hun

Two women with lifelong weight struggles try a new weight loss service - with incredible results!
AD FEATURE

Prince Harry's neighbor Rob Lowe claims Duke now 'has a PONYTAIL' after spotting 'reclusive' royal driving around with 'long hair'

Saved By The Bell's Dustin Diamond, 44, 'hospitalized in Florida after suffering full body pain... as doctors suspect cancer'

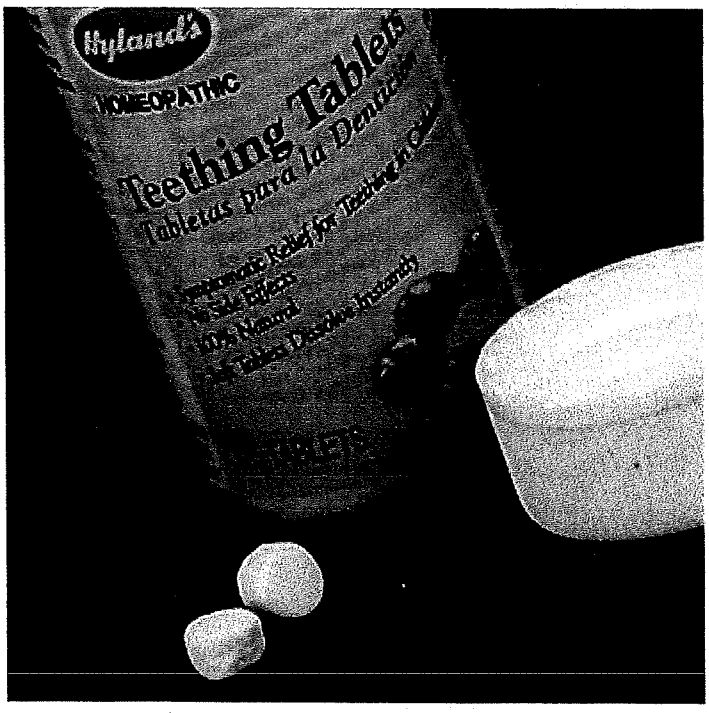
TODAY'S TOP VIDEOS

Exhibit #30

Hyland's Homeopathic Teething Tablets: Questions and Answers

Dec. 18, 2017: The FDA proposed a new, risk-based enforcement approach to drug products labeled as homeopathic (/news-events/press-announcements/fda-proposes-new-risk-based-enforcement-priorities-protect-consumers-potentially-harmful-unproven). More here. (/drugs/information-drug-class/homeopathic-products)

Español (/consumers/articulos-en-espanol/pastillas-homeopaticas-para-la-denticion-hylands-preguntas-y-respuestas)



What action did the FDA take?

On October 23, 2010, the U.S. Food and Drug Administration (FDA) warned consumers to stop using and discard (/consumers/consumer-updates/where-and-how-dispose-unused-medicines) Hyland's Teething Tablets; and the manufacturer recalled the product.

Why did the FDA take this action?

The FDA issued this warning because the use of Hyland's Teething Tablets may pose a risk to children. The FDA's analysis and testing identified some Hyland's Teething Tablets that contained varying amounts of belladonna, a potentially toxic ingredient. The FDA has received

reports of serious adverse events in children taking this product that are consistent with belladonna toxicity. An FDA inspection at the manufacturer's facility indicated substandard control of the manufacturing operation.

The FDA has also received reports of children who consumed more tablets than recommended, because the containers did not have child resistant caps.

What product was affected by this warning?

The FDA's warning affected all lots of Hyland's Teething Tablets. At the time of this warning, the product was widely sold in pharmacies and other retail stores, and continues to be marketed online as an over-the-counter (OTC) homeopathic drug intended to provide temporary relief of symptoms related to teething in children.

What is belladonna?

Belladonna is commonly known as Deadly Nightshade. It is a plant whose leaves and berries are extremely toxic. Belladonna has been used as both a poison and a medicine throughout history.

What are symptoms of belladonna toxicity or overdose?

Belladonna alkaloids have anticholinergic effects. Classic signs of anticholinergic toxicity include fast heart rate, increased body temperature, dry skin and dry mouth, skin flushing, constipation, decreased urination, agitation, disorientation, hallucinations, and dilated pupils. Drowsiness may also be seen in infants.

Are Hyland's Teething Tablets approved by the FDA?

The FDA has not evaluated Hyland's Teething Tablets for safety or efficacy, and is not aware of any proven clinical benefit offered by this product.

What should consumers do if they experience harm related to these products?

The FDA recommends that consumers contact their health care professional if their child experiences symptoms after taking Hyland's Teething Tablets. Symptoms include a depressed level of consciousness, seizure, difficulty or slowed breathing, lethargy, sleepiness, muscle weakness, skin flushing, constipation, difficulty urinating, or agitation.

Health care professionals and consumers should report side effects from use of Hyland's teething tablets to the FDA through the MedWatch program (https://www.fda.gov/safety/medwatch-fda-safety-information-and-adverse-event-reporting-program), by phone at 1-800-332-1088, or online at http://www.fda.gov/medwatch/index.html (http://www.fda.gov/medwatch/index.html)

What further steps has the FDA taken?

On September 30, 2016 the FDA issued another advisory (/news-events/press-announcements/fda-warns-against-use-homeopathic-teething-tablets-and-gels) warning consumers to stop using and to discard (/consumers/consumer-updates/where-and-how-dispose-unused-medicines) or return the Hyland's Teething Tablet product; and the agency's investigation of the product and the firm's manufacturing operations is ongoing.

back to top

Exhibit #31

HEALTHCARE & PHARMA

MAY 27, 2015 / 5:44 PM / UPDATED 6 YEARS AGO

FDA ban nearly wiped out deaths, poisonings from ephedra

By Gene Emery, Reuters Health

NEW YORK (Reuters Health) - A 13-year tally of deaths and poisonings from ephedra show a spectacular (the sale of weight loss products containing the herb in 2004.

"The number of poisonings resulting in major effects or deaths has decreased by more than 98% since 200 limiting the availability of ephedra and therefore its potential toxicity in the United States," Illinois researc

It was the first dietary supplement to be banned.

"I used to see patients with a lot of ephedra problems in the late 1990s and early 2000s. I haven't seen one toxicology at NorthShore University HealthSystem in Evanston told Reuters Health in a telephone intervie

"It's the eradication -- you can almost use that word -- of this substance within a relative short period of tir quite surprising. And remember, this was not a drug. This was an over-the-counter dietary supplement. Th on dietary supplements."

Ephedra, also known as ma huang, was the chief ingredient in many weight-loss and energy-enhancement p short-term weight loss but it was killing people.

It has been linked to heart attack, stroke, seizure, high blood pressure, and heart rhythm problems. It was l prospect Steve Bechler in 2003. It was especially dangerous when used in conjunction with caffeine.

The ban was implemented in April 2004, overturned by the industry in 2005 but ultimately upheld by the U were saying the substance had been used by 12 million people.

Using data from the National Poison Data System, the researchers found that ephedra poisonings peaked a 2013.

Major effects, defined as hospitalization usually requiring critical care, peaked the same year, at 108, one ye such reports were down to three or fewer per year.

The number of deaths peaked later -- at seven in 2004. There had been five, three and six the previous year were none in 2006 and in the years after 2007.

"What kind of surprised us was the near-completeness of the decrease in toxicity, how it went from 8,000 t center," Dr. Leikin said.

He speculated that the initial declines seen just before the ban went into effect could have been the result (

NOW READING FDA ban nearly wiped out deaths, poisonings from ephedra

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Sola Russ
2 HC

crimped by the 1994 Dietary Supplement Health and Education Act. This awful law classifies herbal produc them without proof that they have caused deaths and/or serious injuries. That's backwards."

He said "the law should require that herbal products sold for alleged health purposes be proven safe and ef

SOURCE: bit.ly/1AmGkvY

N Engl J Med 2015

Our Standards: The Thomson Reuters Trust Principles.

Exhibit #32

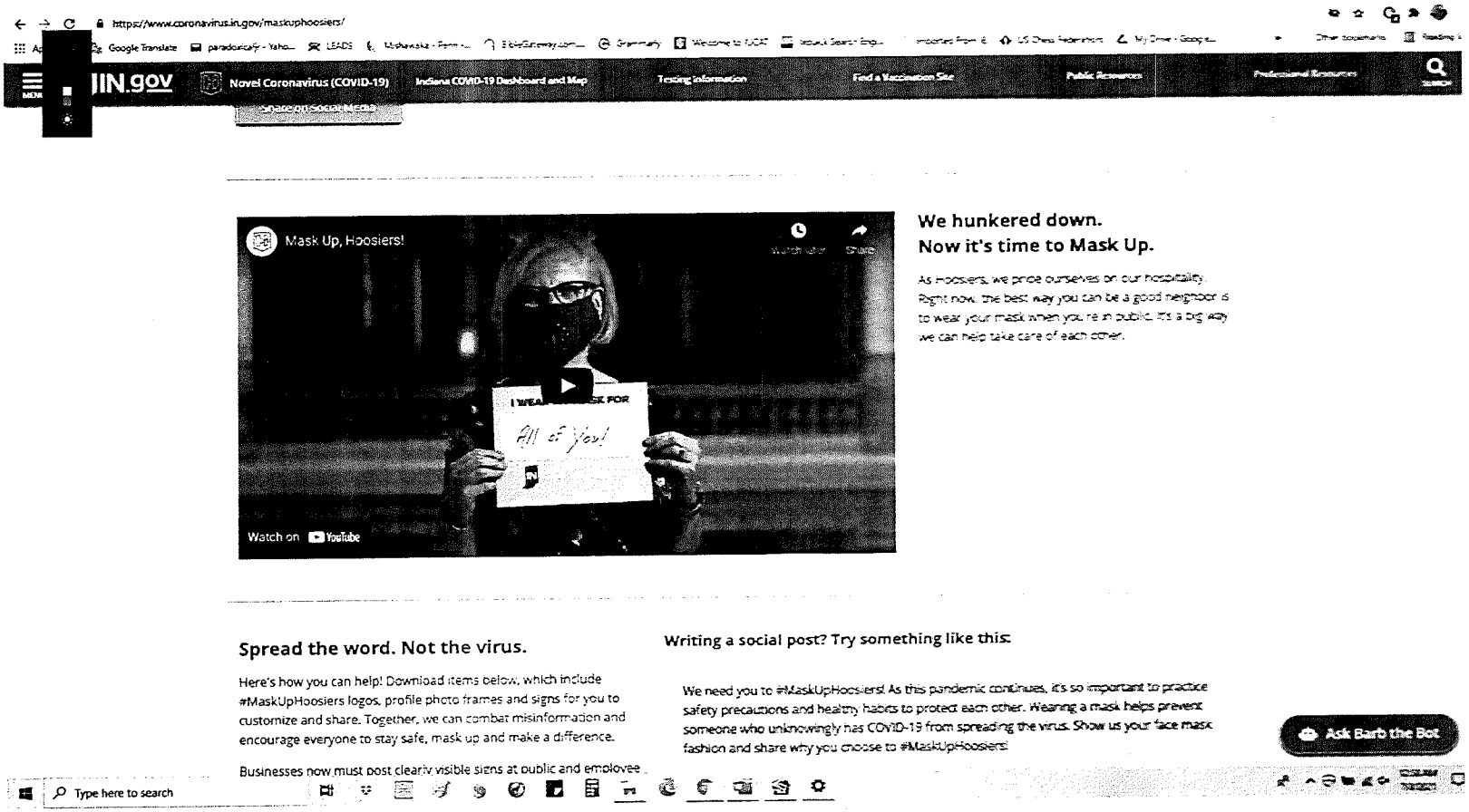

Exhibit #33

https://www.cnn.com/2020/04/03/politics/navy-hospital-ship-comfort-new-york-coronavirus/index.html

Navy hospital ship deployed to NYC with 1,000 bed capacity is only treating 22 patients

By Veronica Stracqualursi and Ryan Browne, CNN
Updated 5:17 PM ET, Fri April 3, 2020

Now PlayingTemporary hospitals set...

(CNN)A US Navy hospital ship currently docked in New York City harbor is treating only 22 patients as of Friday afternoon, despite having a 1,000 bed capacity to treat non-coronavirus patients, according to a US Navy official.

Navy officials told CNN that they expect the number of patients being treated to increase significantly in the coming days as the process of referring patients to the ship is refined.

The USNS Comfort was deployed to New York City, the epicenter of the virus outbreak in the United States, to free up capacity in the city's civilian hospitals so that they can focus on treating coronavirus patients.

New York City's hospitals have been overwhelmed with coronavirus cases and are struggling to respond to patients constantly streaming in. A shortage of personal protective equipment has also placed medical workers at risk of contracting the virus. On Thursday,

New York Gov. Andrew Cuomo announced that the temporary hospital facility at the Javits Convention Center, which holds 2,500 beds, will now treat Covid-19 patients.

New York's governor will sign executive order to allow redistribution of medical supplies to hospitals in need

Asked about the lack of patients being treated by the Comfort, New York City Mayor Bill de Blasio told CNN's John Berman on Friday, "There's no question in my mind that will get resolved quickly. You'll see that number grow."

"Having the Comfort here is a very, very important thing for New York City in terms of the number of patients served, but also an extraordinary morale boost when we needed it," De Blasio said. "I don't have a doubt in my mind, the Comfort will be filled up soon."

Ambulances are not taking people directly to the ship, which docked in New York City on Monday. Patients are referred to the ship by shore-based hospitals and must be screened and tested for the virus before being admitted on board.

Pentagon working to admit patients more quickly

The Department of Defense said Friday that it would begin streamlining the process to admit patients onto the ship.

"Screening for care on the USNS Comfort will be modified and will now occur pier-side in an effort to reduce the backlog at some of the nearby New York hospitals," the Pentagon said in a statement. "The screening effort for the USNS Comfort will no longer require a negative test (for coronavirus), but each patient will still be screened by temperature and a short questionnaire."

There are some patients that the Comfort can't bring on board, mainly those who are immunosuppressed due to the fact the ship is open bay and does not have the ability to isolate patients, according to a Navy official familiar with operations on the ship.

"We are conducting data analysis to see how we need to change our configuration -- bottom line we've been here 48 hours, and this is a scenario no one has ever seen before," the official told CNN. "No one wants to get this wrong. We hear the feedback from medical professionals, and are fine tuning," but the Comfort will still only treat non-coronavirus patients.

Sailors cheer for aircraft carrier commander who was removed after issuing coronavirus warning

On Thursday morning, the Comfort was treating "three" patients, according to Capt. Patrick Amersbach, the ship's commanding officer. A US Navy spokesperson confirmed late Thursday that the number of patients on board the Comfort had reached 20, which The New York Times first reported. Two more patients were admitted on Friday.

"The ship really seems kind of useless," a city hospital physician caring for coronavirus patients told CNN Friday.

The Comfort has more than 1,100 personnel on board to treat patients. It also contains 12 fully equipped operating rooms, radiology services, a medical lab, pharmacy, optometry lab, a CAT-scan and two oxygen producing plants, according to the Navy.

Another Navy hospital ship, the USNS Mercy, deployed to Los Angeles, has treated 15 patients so far, five of whom have since been discharged, Capt. John Rotruck, the ship's medical facility commanding officer, said Thursday.

Rotruck said the Mercy was treating patients recovering from traumatic accidents, heart and lung problems, and gastrointestinal issues.

Temporary hospitals being converted to treat coronavirus patients

The Pentagon also announced Friday that the military will convert three temporary medical facilities in New York, New Orleans, and Dallas into facilities capable of treating patients with the virus.

"At the request of (Federal Emergency Management Agency), the Department of Defense will expand its medical support to include COVID-19 positive patients at the Javits Federal Medical Station (FMS) in New York City, the Morial FMS in New Orleans, Louisiana, and the Kay Bailey Hutchinson FMS in Dallas, Texas," the Defense Department said in a statement.

"These three DoD-supported locations will now provide support to COVID-19 positive patients in convalescent care, as well as low-acuity patients. These patients, who require a lower level of medical care, must first be screened at a local hospital," the statement added.

Originally all three facilities were intended to treat non-coronavirus patients in order to free up capacity at civilian hospitals.

One hospital administrator told CNN that he's relieved the Javits Center will now be used to treat patients with the virus.

"We thought it was completely unrealistic for both the Javits Center and the Comfort to accept non-Covid patients. As a practical matter in New York, everybody's Covid," he said, adding that the "best thing to do would be to move patients who are stable from the hospitals to Javits or to (the) Comfort."

Later on Friday, Lt. Gen. Todd Semonite, commander of the Army Corps of Engineers, said to date, the Corps has received 750 requests for site assessments across the country to look into possible facilities that could be used in the coronavirus response. Semonite said the Corps has completed 673 of those site assessments.

He said to date, the Army Corps of Engineers are "not resource strained" in terms of being able to carry out site assessments as they continue their work running and setting up treatment sites across the United States.

CNN's Brynn Gingras, Sonia Moghe, Shimon Prokupecz, Jamie Crawford, Meg Wagner, Mike Hayes and Christina Maxouris contributed to this report.

Exhibit #34

https://www.kiro7.com/news/trending/21-million-hospital-built-coronavirus-victims-new-york-closes-without-ever-seeing-patient/Q3MJKWG3ENB23N3NPR7CVTWOIU/

$21 million hospital built for coronavirus victims in New York closes without ever seeing a patient

May 26, 2020 at 9:52 am PDTBy Jared Leone, Cox Media Group National Content Desk

NEW YORK — A temporary field hospital built for $21 million as the coronavirus outbreak threatened to overrun medical facilities in New York has closed without ever seeing a patient.

Plans to transform the Brooklyn Cruise Terminal into a temporary 670-bed hospital were announced March 31, a day after the USNS Comfort hospital ship arrived to help coronavirus patients. Officials also announced a tennis center in Queens would be converted into a 350-bed facility.

At that time, there were about 8,400 patients in hospitals citywide being treated for the coronavirus, The City reported.

The tennis center opened as a medical facility April 11 when there were 12,184 patients in hospital beds being treated across the city. It cost $19.8 million to renovate and revert the tennis center. It closed earlier this month after taking in 79 patients.

The Brooklyn hospital, built by SLSCO, a Texas-based construction company, was supposed to open in April but was not ready for patients until May 4, The City reported. By then, hospital use had been sliced in half, to about 6,000 patients. It closed last week without ever having a patient.

The Federal Emergency Management Agency is expected to pay the costs for both hospitals.

The two field hospitals were not the only emergency medical facilities in New York that saw limited use.

The Comfort left New York after about a month and treating 182 patients, of which about 70% had the coronavirus.

Several other field hospitals were built across New York for nearly $350 million. They closed in April without seeing any patients, The Associated Press reported.

Built for worst-case scenarios, some of the unused facilities will be kept on stand by for a possible second wave.

"As part of our hospital surge, we expanded capacity at a breakneck speed, ensuring our hospital infrastructure would be prepared to handle the very worst. We did so only with a single-minded focus: saving lives," city spokesperson Avery Cohen told The New York Post. "Over the past few months, social distancing, face coverings, and other precautionary measures have flattened the curve drastically, and we remain squarely focused on taking that progress even further."

Emergency Hospital FILE PHOTO: Many field hospitals went largely unused and will be shut down. (Stephanie Keith/Getty Images)

The Associated Press contributed to this report.

Cox Media Group

Exhibit #35

PHILOSOPHICAL TRANSACTIONS OF THE ROYAL SOCIETY B

rstb.royalsocietypublishing.org

Interview

Cite this article: Henderson DA, Klepac P. 2013 Lessons from the eradication of smallpox: an interview with D. A. Henderson. Phil Trans R Soc B 368: 20130113.
http://dx.doi.org/10.1098/rstb.2013.0113

One contribution of 15 to a Theme Issue 'Towards the endgame and beyond: complexities and challenges for the elimination of infectious diseases'.

Subject Areas:
health and disease and epidemiology

Keywords:
smallpox, disease eradication, interview, poliomyelitis, guinea worm

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Lessons from the eradication of smallpox: an interview with D. A. Henderson

D. A. Henderson[1,2] and Petra Klepac[3]

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[2]Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA
[3]Department of Applied Mathematics and Theoretical Physics, University of Cambridge, Cambridge CB3 0WA, UK

It has been more than 35 years since the last naturally occurring case of smallpox. Sufficient time has passed to allow an objective overview of what were the key factors in the success of the eradication effort and what lessons smallpox can offer to other campaigns. Professor D. A. Henderson headed the international effort to eradicate smallpox. Here, we present a summary of D. A. Henderson's perspectives on the eradication of smallpox. This text is based upon the Unither Baruch Blumberg Lecture, delivered by D. A. Henderson at the University of Oxford in November 2012 and upon conversations and correspondence with Professor Henderson.

1. Introduction

Before smallpox eradication was attempted, four other eradication efforts had failed [1–3]: namely; hookworm, yellow fever, yaws and malaria. The malaria eradication campaign was particularly extensive and intensive both in terms of manpower and financial resources (more than $2.5 billion expended from 1957 to 1975) [4]. These failures eventually led many in the global health community to shift their focus from targeted disease-eradication attempts to less explicitly defined programmes such as providing basic health services. There was a perception that eradication programmes, referred to as 'vertical programmes', could have a particularly deleterious impact in inhibiting the development of the basic health services (so-called 'horizontal' or 'integrated' programmes). Thus, a proposal to undertake a global smallpox eradication campaign was a divisive and politically charged issue, further complicated by the fact that the World Health Organization (WHO) was reluctant to support another eradication campaign. However, in 1966 the World Health Assembly (WHA) passed a resolution approving an annual budget of $2.4 million to support a 10-year smallpox eradication plan by the very narrow margin of two votes (58 were needed for approval, it received 60) [1].

2. Interview

(a) How did the smallpox eradication programme start, and how was it received?

During the 1960s, expenditure for the malaria programme represented 20 per cent or more of all funds available to WHO, thus constraining other control programmes. By the late 1960s, it became apparent that the programme would be far more costly and take far longer than many anticipated. An increasingly prevalent view was that disease eradication was not possible (see Rene Dubos' book *Man Adapting* [5]). This was the view of the Director General of WHO in 1966, Marcelino Candau.

Principal direction of the malaria programme had been provided by an internationally recruited WHO staff of some 500–600 specialists. National malaria staff operated entirely separately from in-country basic health services. The heads of national malaria programmes reported to the heads of state, not to the Ministries of Health (MoH). Those who worked in the malaria programme

were usually paid somewhat more than those in the basic health services, which enabled the recruitment of some of the best people into the malaria programme. Understandably, this had substantial negative repercussions on the development of health services in countries where the malaria programme was operating.

With the growing problems in the malaria eradication programme, it would seem unlikely that a proposal to undertake the eradication of a second disease would be well received. However, the proposal to eradicate smallpox originated from an unexpected source—the Soviet Union. The Soviet Union and several of its allies returned to participation in WHO (and other United Nations agencies) after years of absence. One of its first acts, in 1958, was to propose that WHO undertake a smallpox programme. Victor Zhdanov, a virologist and deputy minister of health for Russia, called on the WHA to undertake the global eradication of smallpox, even quoting the favourable views of Thomas Jefferson while doing so. At the subsequent Assembly, the proposal was approved by acclamation. Other countries had been pleased that the Soviet Union had decided to return to full participation in WHO and were anxious to exhibit a sense of solidarity. However, over the next 7 years, little progress was made. WHO allocated limited funds, and voluntary contributions by countries were sparse. In 1966, at the request of the Assembly, the Director General drew up and presented a 10-year plan. It had two components: (i) systematic vaccination and (ii) a new concept—surveillance and containment. The latter called for weekly reports of cases from all health facilities and containment of outbreaks by special containment teams. It called for a WHO budget contribution of $2.4 million per year; voluntary contributions were expected to supplement this. Many countries doubted that eradication was possible and others were reluctant to agree to increasing their budgetary assessment by the amounts that would be required. The eradication plan was put to a vote. The Assembly, which normally reaches decisions fairly quickly and by acclamation, debated for 3 days on this proposal, and in the end put it to a vote. The resolution was passed by the narrow margin of two votes.

(b) How did the US get involved in the smallpox eradication efforts when it was initially opposed to it?

The US got involved indirectly. In the 1960s, I was at the US Centers for Disease Control (CDC) in charge of the surveillance section, mainly for viral diseases, smallpox, measles, flu, and so forth. I had approximately 40 staff; some were stationed at our Atlanta headquarters; others were in state and local health departments. In the early 1960s the National Institutes of Health (NIH) staff and Merck became interested in the possible use of a new Merck measles vaccine in African countries where measles was an often fatal disease. In the US, measles vaccine was given together with gamma-globulin to diminish the possibility of high fever sometimes associated with administration of measles vaccine. Use of gamma-globulin with the vaccine would not be feasible for countries with limited health services. Thus, they wanted to undertake a study of the effects of vaccine without immunoglobulin. An NIH-led study in Upper Volta (now Burkina Faso) showed and had few adverse reactions [6,7]. The government in Upper Volta supported the study in return for enough vaccine for all of its children, and US Agency for International Development (USAID) indicated its willingness to cover the costs. Upper Volta was a member of L'Organisation de Coordination et de Coopération pour la Lutte contre les Grandes Endémies (OCCGE), a consortium of nine former French colonies in western Africa that collaborated in providing preventive and health services. This organization pressed USAID and Merck to make measles vaccine available for all children in these countries during the course of a 4-year programme. It would require training national teams from each country. As the focus of NIH was research, and not field operations, the CDC was asked to assume this role.

I thought the programme was a bad idea. The programme was expected to vaccinate 25 per cent of the children each year after which the countries would be expected to bear the costs for continuing vaccination. At that time, the measles vaccine cost $1.75 a dose, but the countries could not even afford 10 cents per dose for yellow fever vaccine. Starting and then stopping a vaccination programme in this manner was bad public health practice. It occurred to us that if a smallpox vaccination programme were instituted, it could be sustained, as smallpox vaccine cost only 1 or 2 cents a dose. Thus, we decided to propose a combined smallpox eradication–measles control vaccination programme. This would at least leave some structure and sustainable activity for smallpox control as a legacy.

We believed we could stop smallpox transmission in particular countries but, with the many nomads moving through West Africa, a region-wide programme would be necessary for effective smallpox control and perhaps to stop transmission. Thus, we suggested to USAID that the proposed programme be extended to 18 countries. This would have to include Nigeria, which constituted 67 per cent of the population of the whole area. The budget we proposed, $35 million over a 5-year period, was substantially greater than the $7 million that USAID had expected to spend. Much to our surprise, the proposal was accepted in full by President Johnson as a special US contribution to a United Nations initiative called 'International Cooperation Year'.

We were only six months into this programme when I was called to Geneva to help WHO draw up the Director General's plans for the global smallpox programme which was to be presented months later at the May 1966 World Health Assembly. With full support now of the 18 West African countries, a positive decision for WHO to proceed with the global plan became a certainty. Subsequently, the Director General decided that an American should direct the entire programme. Thus, in less than a year I had moved from director of a CDC surveillance programme to director of an 18-country smallpox eradication–measles control effort and finally to the position of Chief Medical Officer for the global smallpox eradication programme.

(c) At what point did it become clear that you would make the 10-year goal to eradicate smallpox?

Initially, the 10-year plan was little more than a theoretical hope. We had very little to work with in the planning—the data on reported cases were very incomplete and we had almost no information on what countries were doing already

gradually transitioned to expectation but confidence that eradication could be achieved was not there until 1975.

About 4–5 years into the programme, we had begun thinking that eradication within another 3–4 years might be feasible. The West African programme had proceeded so well and so rapidly that it stunned everyone. This was a group of countries that included those with the highest incidence of smallpox in the world but, at the same time, had the least developed communications and transportation systems and the least sophisticated health services. The plans that we had made were substantially more successful than we had anticipated. Most of East Africa also became smallpox free only a few years later. From 1967 to 1973, the number of smallpox endemic countries dropped dramatically—from 31 to only five—India, Pakistan, Bangladesh, Nepal and Ethiopia. South Asia was a formidable problem and a heavily populated area. Significant changes had to be made in the strategy; resources had to be augmented—both in cash and people. The concluding barriers—Ethiopia and Somalia—posed other problems. Ethiopia was engulfed in civil war; teams in Somalia were handicapped by government officials refusing to report cases until they became epidemics. But, finally, on 26 October 1977 the world's last case of smallpox was discovered in Merka, Somalia.

(d) You suggested that surveillance-containment was not the ultimate magic bullet that alone made the programme so successful. Could you expand on this?

A distinctive element of the programme, even more critical than surveillance-containment, was a heat-stable vaccine of assured potency, and a better technique for vaccination. Fortunately, Leslie Collier, of the Lister Institute, in the 1950s, had developed a commercially practical method for producing a freeze-dried vaccine that could withstand a temperature of 37°C for more than a month [8]. This was essential for all tropical areas. As we came to learn, however, it was in use in only a few of the more than 40 laboratories then making vaccine by some process. Quality control, if used at all, was to vaccinate some 8–10 rabbits or people and to use the vaccine if most developed some sort of lesion. With the help of a Dutch and a Canadian laboratory, we sought to obtain independent quality-control testing. The results were to show that for all vaccines intended for use in the programme in 1967 perhaps 80 per cent or more were seriously substandard and vaccine failures were frequent [9]. We recruited consultants from major laboratories to write a working production manual and they provided help and advice to laboratories in the developing countries. UNICEF provided commercial-sized freeze-drying machines. By 1973, all vaccine met potency, purity and stability requirements. Usage of a newly invented bifurcated vaccination needle (figure 1) in 1966 was another key element [10]. The needle was inexpensive, easy to use and required only a quarter of the vaccine dose normally required. Training of vaccinators required no more than 15 min and vaccinators could readily average 500 vaccinations per day obtaining more than 95 per cent successful takes.

A certain amount of vaccination was already being done by

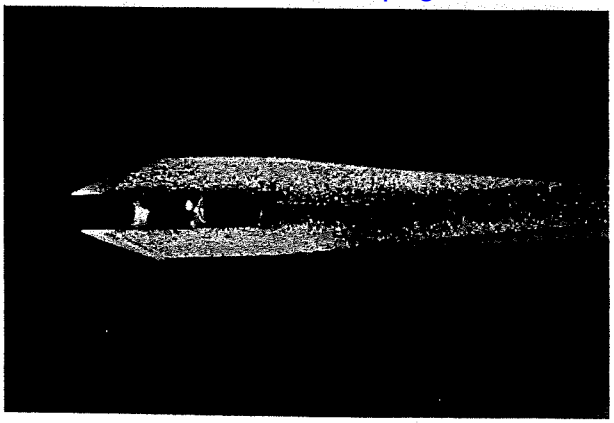

Figure 1. Bifurcated needle. Photo credit: CDC. (Online version in colour.)

and Kenya, Uganda, Tanzania and Malawi eliminated smallpox even before they could establish surveillance-containment programmes [6].

(e) In India the surveillance-containment system had to be modified—how and why?

A basic component for smallpox surveillance was a weekly report from each health centre or hospital regarding each case of smallpox seen or a report stating that there were no cases. A team of two or three was then to go to the area, vaccinate all those in the immediate area and, in the process, search to see if there were other cases (figure 2 shows a team searching for cases). India provided for reporting from health units but the reports progressed through a hierarchy of offices, usually being delayed at each stop and sometimes changed. With a highly mobile population of 550–600 million, cases were usually reported too late for containment, if reported at all. More timely detection was essential. Accordingly, surveillance in India was augmented to focus on routine, repetitive active searches for cases—130 000 health personnel periodically swept through states searching every village and, eventually, every house during a 10-day period. The aim was to search 90 per cent of houses every two months to discover outbreaks and for containment vaccination teams to follow. Initially, the searches discovered tens or even hundreds of cases where none at all were being reported. With time, however, performance improved with the result that the last case in India was discovered little more than 18 months after the first search was undertaken [11].

(f) You mentioned that in more sparsely populated areas, special search programmes were important for the surveillance-containment programme. What was the nature of these?

In low-density areas, one has the particular problem of having very few or no health personnel. However, as we discovered, there are always well-demarcated places where people regularly come together, such as markets or religious centres. In Ethiopia, people came to markets once a week, walking 10–15 miles to reach them. In Indonesia, we discovered the importance of schools—that it was possible for one worker to obtain a list of outbreaks over a wide area by going to schools

Figure 2. Schoolchildren and the Smallpox Recognition Card. Schoolchildren are being shown the WHO smallpox recognition card and asked if they know of cases. Information about cases within a 10 km (6.2 mile) radius was usually known to children who were between 8 and 12 years of age.

villages, indeed which houses had smallpox. We came to learn that children between 8 and 12 years know almost everything that's going on in their own village and they are happy to share that information.

(g) Is there any other disease that you would foresee being eradicated?

No. Not at this time given presently available relevant technologies, our understanding of the epidemiology of the infectious diseases, and pilot programmes of national disease elimination programmes. The one exception is guinea worm disease. A programme to eradicate it is progressing well, albeit it is in its 27th year, 13 years beyond the target date that had been set. Civil strife, however, continues to hamper it.

I believe that this is essentially the same answer that Frank Fenner, the world-renowned Australian virologist, and I provided in August 1980 at a meeting on eradication called at the Fogarty Center in Washington. The meeting was held only three months after the World Health Assembly meeting in Geneva had declared officially that smallpox had been eradicated. The mood of the 1980 meeting was a surprise to us both. We were well aware of the realities that we had encountered in smallpox eradication and the heroic efforts made by our own and national staff to achieve eradication. It was difficult to conceive of another disease problem that could similarly be addressed. However, the meeting theme was basically to decide *what next* should be slated for eradication. Frank Fenner and I were the keynote speakers, and both of us said, we did not think that at this point in time there was any candidate disease. Not surprisingly, the message was not welcomed. Subsequently, neither of us were invited to any of the many following meetings on eradication which have been conducted.

(h) Can you tell us your views on the guinea worm programme?

Many of the lessons of smallpox eradication were directly translated into the guinea worm programme; in particular, a strong emphasis on reinforcing surveillance and feedback coupled with regular rotations into the field by senior management personnel; as well as a considerable emphasis on community involvement. This includes educating the local people and the village chiefs about disease-prevention methods as well as the need for early identification and treatment. Filters for water purification and better water supplies also are making a difference. The programme is tied to the UNICEF provision of water programme, in order to accelerate the sinking of wells in many places. However, a major challenge for the eradication of guinea worm is civil disorder.

(i) What do you see as being other benefits of the smallpox eradication programme?

First was the realization by health administrators in many countries that major improvements in the health status of its people could be effected even with small budgets and a paucity of well-trained health staff if goals were clear and steps were taken to involve local residents in the programme. Many weak, poorly managed primary healthcare programmes benefited from the smallpox programme, focusing, as it did, on greatly neglected vaccination initiatives. To achieve surveillance goals, weekly reports that provided feedback to field staff demonstrated a national interest in otherwise routine reports and improved morale of many in isolated primary care units. For example, the weekly smallpox surveillance programme in Brazil lead to the creation of the Brazil Weekly Epidemiological Report, a report that continues to be published today. Finally, it was the smallpox programme that provided the base and impetus for the launch of the follow-on Expanded Programme on Immunisation (EPI) whose genesis dates back to a first exploratory WHO meeting we had helped convene in 1970.

(j) Can you tell us more about the Expanded Programme on Immunisation, its success in the Americas, and consequences in terms of belief in polio eradication?

The EPI was approved by the WHA in 1974. It emphasized the expansion of mobile vaccination efforts to include other vaccines in addition to smallpox—measles, polio and DTP (diphtheria, tetanus, pertussis). These vaccines had been thoroughly tested and were recommended for routine use in many countries. It would also represent an important initiative in emphasizing disease surveillance as a vital tool in understanding disease epidemiology, in monitoring progress in the programmes and in identifying problem areas and situations. The most successful of the programmes was in the Americas [13], where it was directed by Ciro de Quadros, the Pan-American Health Organization's (PAHO) programme director, a Brazilian and former senior WHO smallpox eradication advisor in Ethiopia. Success in controlling polio led countries of the Americas to agree to undertaking special EPI efforts that could lead to polio elimination. Surveillance networks were strengthened, a polio laboratory network was established, and a concept called 'vaccination days' was perfected [14]. This called for giving oral polio vaccine to all children under 5 years of age throughout an entire country on a single day. This began in Brazil and subsequently was replicated in many other countries [15,16]. A well-defined hemisphere-wide pattern of

evaluations, provisions for laboratory diagnosis and inter-country cooperation, emerged in the Americas. In 1985, de Quadros proposed that polio eradication be established as a hemisphere-wide goal and this was approved by the PAHO Directing Council. The goal was to have the last case by 1990. The goal was missed—by about eight months—but a blueprint had been developed and subsequently thoroughly field-tested.

Progress in the elimination of polio in Latin America provided an incentive for a global programme called for in the Declaration of Talloires in 1988 [17,18] and approved later that year by the WHA. It was an emotional rather than a rational decision. There was no plan or budget. The principal proponents included the US delegation (technical advisors being primarily CDC staff), de Quadros, Albert Sabin, the creator of the oral polio vaccine, Rotary International that had committed financial support for vaccine purchase, and James Grant, the Director of UNICEF.

Concern about polio was entirely that of the industrialized countries with the US playing a predominant role. During the 1940s and 1950s, many infectious diseases faded in importance in the industrialized world. Antibiotics became available, housing, sanitary and nutritional standards improved and DTP vaccine came into use. Many infectious diseases declined to the point of being minor problems. Meanwhile, the incidence of polio increased, as did survivors who were left with visible and handicapping paralyses. Concern about polio increased sharply. With the support of President Franklin Roosevelt, himself a partly paralysed survivor, a special foundation called the National Foundation for Infantile Paralysis was created to raise funds for treatment and research. It was remarkably successful and it was responsible for funding the research laboratories that created polio vaccine. A vaccine comprised of inactivated polioviruses was perfected by a virologist, Jonas Salk, and began to be widely used beginning in 1955 [19]. It was given by injection. A second vaccine, comprised of living polioviruses that could be given by mouth, was developed by Albert Sabin. It became available in 1962 [20]. The oral vaccine soon became the more widely used because it was so easy to administer and inexpensive. It was especially suited for countries where health services were less developed. It was readily accepted in all countries [21].

In virtually all countries, oral vaccine rapidly replaced the inactivated vaccine, which could only be given with syringe and needle. Large-scale vaccination programmes using the oral vaccine were widely promoted in Latin America and a number of other developing countries. The number of cases of polio decreased rapidly. From the time of first use of the oral vaccine, Sabin actively promoted its widespread use in campaigns. As was discovered, such campaigns could be reasonably easily organized and were popular with politicians and the public. Rotary International took up the challenge of making the vaccine more readily available and pledged to raise $100 million by 2005—the 100th anniversary of its founding.

Sabin was especially articulate and insistent on the concept of intensive mass use of his vaccine throughout a country and demonstrated the disappearance of polio in Cuba following just such a programme [22]. Other programmes in the Americas led to the decision in 1985 to eliminate polio from the Americas by 1990. It was on this wave of enthusiasm that a global programme was decided in 1988.

In the discussions about global polio eradication, there correctly, that polio was not a major problem in the developing countries—that it certainly was not ranked among the top 20 or 25 disease problems in most. Accordingly, it was proposed that the bulk of the additional cost (above expenditures for the EPI) be borne by the industrialised countries, as they were the ones who would most greatly benefit. Potential donors pointed out that the provision of special polio funds for vehicles, personnel, etc. would flow through the EPI thus indirectly strengthening that programme.

(k) Can you detail some polio-specific problems, and post-elimination issues?

The oral polio vaccine (OPV) has several characteristics that were not recognized until many years after licensure. However, from the time of licensing of OPV more than 50 years ago it was clear that the vaccine strains are somewhat unstable genetically and could occasionally revert to virulent form. One case of paralytic disease in a vaccinee or close contact occurred in every one to three million vaccinees [23]. This did not deter the use of the vaccine because the benefits of immunity from vaccination considerably exceeded the risk of acquiring the disease. As the number of cases diminished, this complication became of increasing concern.

Wholly unrecognized at the time of licensure was the fact that the poliovirus could combine with certain strains of another virus (Coxsackie) and exhibit other characteristics of persistent growth and spread [24]. The vaccines are referred to as recombinant strains or vaccine-derived polioviruses (VDPVs). These have been shown to be excreted long-term by immunocompromised persons [25] and even healthy individuals [26], and can lead to outbreaks of polio [23]. While vaccine-derived type 1 and type 3 polioviruses only rarely cause small outbreaks and seem to die out in the environment [27,28], type 2 poliovirus is puzzling. A case of the wild type 2 strain has not been seen since 1998. However, the recombinant type 2 vaccine strain has caused unexpected problems in causing cases and continuing to spread. The largest outbreak of recombinant type 2 poliovaccine virus in Nigeria included 278 confirmed cases from January 2005 to June 2009 [29]. Some have suggested that the attack rate and the severity of the disease caused by the recombinant strains are similar, if not identical, to those caused by the wild polio viruses [29] but this needs to be confirmed by more complete epidemiological data than has yet been made available (see [30]).

Furthermore, wild polioviruses can circulate undetected, despite surveillance, for up to 5 years, as has happened at least once (in Sudan [31]). Thus, certification of eradication will require at least 5 years with continued control and surveillance but using OPV during this time increases the risk of circulating recombinant vaccine viruses. How important this may be is uncertain as the recombinant strains of types 1 and 3 seem to die out spontaneously and after only a brief spread. How long a type 2 recombinant may survive is unknown. Only careful epidemiological–virological studies will tell. Consideration has been given to substituting inactivated polio vaccine for the oral vaccine but this is at least 20 times more expensive per dose and must be administered percutaneously and so requires more manpower and needles/syringe. It is impractical for use in slum areas where immunity after the OPV results from local spread of

It is difficult at this time to visualize a feasible, affordable and supportable 'endgame' to achieve polio eradication as it is now defined—the complete cessation of transmission of all wild poliovirus strains and vaccine-derived strains.

(l) Why were you sceptical about polio/other eradication efforts?

A simple answer is to point out that I had spent 11 years of my life endeavouring to eradicate smallpox and I knew well the diverse array of problems that a programme has to navigate. Smallpox eradication proved to be infinitely more difficult than I or anyone else had imagined it would be. Indeed, it is all but a certainty that any of a number of obstacles could have blocked its completion at various points in the programme but fortunately, in each case, unexpected events or special measures intervened to resolve problems.

Little had I appreciated the magnitude or number of other imponderables—floods, wars and famines, hundreds of thousands of refugees, national bureaucracies and constraints that rivalled the US in number and complexity, a difficult USAID programme (an unwilling but a significant contributor), and a sclerotic WHO administration that often thwarted or actively impeded what appeared to be logical initiatives.

There were other unexpected events—changes in governments, fortuitous laboratory discoveries, unexpected successes in launching vaccine production operations in developing country laboratories, and the emergence of needed leadership and courage by national and international staff at numerous critical points. The programme was ultimately successful but success hung in the balance on many occasions.

From my examination of the characteristics and needs for eradicating other diseases, each has prominent features that makes it far more difficult than smallpox. With smallpox, we had a vaccine so heat stable that teams travelled in the field without refrigeration devices. We had a vaccine that provided long-term protection with one dose. One could ascertain whether vaccination was successful by determining whether or not a pustule had developed at the vaccination site. There were no patients with subclinical infections. Thus, we could readily identify infected areas and contain the outbreaks. Cases were so typical and so readily identified that special diagnostic laboratories were unnecessary.

There are very few eradication enthusiasts who have had real-world practical experience in executing a successful component of an eradication programme at the local or national level and there are even fewer who have had the opportunity (or taxing challenge) of dealing with the practical and political complexities of a targeted programme at national and international levels. Prospects for eradication appear far more optimistic from the vantage point of a laboratory or an office in a university ivory tower.

(m) The original target established by the WHA was to eradicate polio by 2000. Since then, the Global Polio Eradication Initiative had a number of extensions to this deadline. What is different about the latest extension?

Four previous 3 year extensions for the target date of polio in 2000, 2004, 2007 and 2010. Each called for an ever more intensified, more heavily supported universal effort but none succeeded. A fifth further intensified effort was announced in 2013. National and international leaders have pledged and are providing their full support, Bill Gates and the Gates Foundation have made polio eradication a special cause. It is recognized that the success of polio eradication has important implications for the successful and expanding global EPI.

(n) Why do you think eradication programmes are so popular?

There is a belief that unless eradication is set as a goal, governments will not be willing to contribute the necessary resources for infectious disease control. To me, this seems like a weak excuse for inadequate efforts on the part of public health staff to educate and to persuade.

3. Final words

The guinea worm programme, as well as smallpox eradication, offer important prototypical examples. They have steadily evolved over time in response to the practical realities encountered in the field, the development of new approaches through research, the active involvement of local leadership and peoples, and imaginative quality control measures and supervision. Each developed different approaches and strategies adapted to local conditions. The polio programme had similar successes in eliminating polio from the Americas during the period 1985–1991 [32]. But the challenges in geography, populations and infrastructure of Asia and Africa have been overwhelming. The programme has struggled to develop satisfactory surveillance programmes for an elusive disease which has countless subclinical infections and which requires a sophisticated virus laboratory for confirmation of cases. An equally formidable obstacle has been the challenge of providing hundreds of millions of doses of a fragile, heat-labile vaccine throughout vast tropical and sub-tropical areas with limited health and transportation infrastructures. That not one but multiple doses of vaccine are required to provide assured immunity makes the task even more forbidding. Nevertheless, the number of infected areas has gradually been constricted, well-trained and motivated staff are working in the field, and resources far beyond any ever committed to control of a disease are being steadily made available. Hope is expressed that transmission of wild poliovirus will be stopped by the end of 2015, that circulation of recombinant poliovaccine viruses will be able to be stopped as well within the following 2–3 years. Success would be welcomed indeed by everyone.

Whatever the outcome, experiences to date with eradication programmes should be cautionary to any who contemplate an eradication effort. Disease control and elimination programmes can be varied in intensity and duration. Their success or failure is usually of limited importance to other countries. Eradication is a different story. It represents a global commitment from which it is problematic for countries to withdraw however unimportant the disease may be nationally. As investments in a programme grow, the penalty for failure is perceived to

cost financially and to other programmes? The polio programme is now in the 25th year of what was intended to be a 12-year effort.

From experiences to date with eradication programmes, it seems apparent that at least four factors should be in place before a launch: a reasonably thorough plan, an established research programme, success in a significantly large demonstration site, and a firm commitment by a majority of countries with definitive concerns and resources to support a programme. In light of the fact that there has been only one success among the seven global eradication programmes launched to date, the implications of possible failure should be clearly stated as well.

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Exhibit #36

Epidemiological Section.

October 27, 1911.

Sir SHIRLEY MURPHY, Vice-President of the Section, in the Chair.

Plague in Manchuria.

By REGINALD FARRAR, M.D.

DURING the winter of 1910-11 Manchuria was ravaged by an outbreak of pneumonic plague, which recalls some of the historic outbreaks of the Middle Ages, but to which modern times afford no parallel.

When compared with the mortality caused by bubonic plague in India, the actual proportions of the Manchurian epidemic do not seem large, but it captured the popular imagination by reason of the dramatic features which attended it, its mysterious origin, rapid spread, and appalling virulence.

I will pass lightly over the features which intensified the dramatic interest of the outbreak, before considering those facts which have a more serious interest for ourselves as epidemiologists.

The Manchurian plague outbreak has in a high degree the fascination that belongs to all that is Oriental and mysterious. The disease is believed to have been transmitted to man by the tarabagan, a large marmot inhabiting the remote wilds of Siberia and Mongolia. The first human victims claimed were probably trappers who hunt and trap this animal for the sake of its fur. After an explosive outbreak in Manchu-li, the frontier town of Siberia and Manchuria, and in Harbin, it was rapidly carried south along the railway and the roads by the hordes of Chinese coolies from Shantung, who migrate every year into Manchuria for the soya-bean harvest, and return home to worship their ancestors at the Chinese New Year. The plague travelled through Manchuria,

the Tartar province whence issued the present Manchu dynasty, the conquerors of China, by a route every mile of which has been fought over by the Russians and Japanese, to whom Manchuria is as Naboth's vineyard, along railway lines which are partly Russian, partly Japanese, and partly Chinese. In consequence, the difficulties of sanitary administration were enormously enhanced by international diplomatic complications. The virulence of the infection was such that in many instances whole families and large households were mown down by the disease, and its fatality so appalling that out of more than 40,000 cases only three recoveries are claimed. Those who took the disease passed rapidly into a stuporous condition and died generally within forty-eight hours. Men walking along the streets would be observed to stagger, reel, and fall. Where they fell, there they lay crouching, for none dared succour them. They passed from stupor into coma, and died shunned and untended. The poor corpse lay frozen stiff in the attitude of death by the bitter cold, till the burial coolies came and dragged it away with ropes and hooks. None dared give shelter to a stricken patient, and the sick were often thrust out into the streets to die, lest their death should implicate the household. Those who died were often hidden in the "k'angs" or under the roofs of their houses, or in other places of concealment.

Burial was impossible, for the temperature of Manchuria in winter is often 40° F. below zero, and the ground is frozen hard to a depth of more than 3 ft. Eventually sanction was given—for the first time in Chinese history—to cremation, and in several towns piles of bodies—coffined or uncoffined—that had been lying unburied for weeks were burned on pyres or in huge pits.

The sick were tended in hospital by mysterious figures swathed from head to foot in white robes and hoods, their eyes concealed by goggles and their features by gauze masks, like members of some awful Vehmgericht whose doom was certain death. In several instances those that tended the sick fell victims to the plague—the French Dr. Mengy, two French Sisters of Charity in Chi-fu, the Russian Marmontoff, Dr. Jackson, of Moukden—whose funeral oration, spoken by the Viceroy of Manchuria, is a monument of Chinese eloquence—and others.

The dread of plague was over all society. In stricken towns commerce and social intercourse were at a standstill. Those of stricken households were refused admission into shops or into the homes of their friends and kinsfolk, and often depended for sustenance entirely on food left by neighbours outside their doors.

The guards at the city gates, the police in the streets, the railway military guards, all wore masks, and many private citizens would not venture abroad without a mask. A gauze mask was an indispensable part of the uniform of every Japanese soldier in Manchuria for several months, and was conscientiously worn, whereas the Chinese soldiers and police were often content to wear theirs round their necks. When Dr. Petrie and I visited Schuang-cheng-fu we were preceded by a military escort of sixty cavalry with band and banner. All the escort wore masks, and even the commander of the escort carried a gauze mask, worn as a sword-knot. In Chi-fu the attempt to induce contacts and the travelling coolies in inns to wear masks was only successful when these masks were stamped in vermilion with a temple seal, and so could be regarded as amulets.

I have said enough to indicate and to explain the profound impression made by the plague in Manchuria upon the Government and upon society generally. When, however, we come to consider in cold blood the actual extent of this epidemic, we are surprised to note that its real proportions were, in fact, relatively small; we find that it was brought under control with comparative ease, despite the complete absence at the moment of its outbreak of an organized sanitary service in China; and the limitation of the epidemic rather than its extension is found to be the factor that requires explanation.

The number of plague deaths in Manchuria as ascertained by careful official computation was 43,972, and if we allow for the few cases that occurred outside Manchuria, and for deaths concealed or otherwise not ascertained, we shall be justified in assuming that the total mortality was little, if at all, in excess of 45,000.

It is impossible to estimate with any degree of accuracy the fluctuating population of Manchuria, and the official returns cannot be regarded as trustworthy, but it has been computed on good authority to be about twenty millions. In this computation thirteen millions are assigned to the Province of Feng-tien, five millions to Kirin, and two millions to Heilung-chiang. On this basis the attack-rate would be about 2·25 per 1,000 of population, and as practically all cases were fatal, the total mortality would be in the same ratio. It must, however, be remembered that the incidence of the disease was almost entirely confined to towns in the railway zone, or in its neighbourhood.

When we remember that plague has caused a total mortality of